California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA

Enforcement Committee and Work Group On E-Pedigree Meeting

Contact Person: Virginia Herold
(916) 574-7911

Date: March 11, 2009
Time: 9:30 a.m. – 4:00 p.m.
Place: Holiday Inn San Diego Bayside
4875 North Harbor Drive
San Diego, CA 92106
(619) 224-3621

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tessa Fraga at (916) 574-7912, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

MEETING AGENDA

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order 9:30 a.m.

A. Workgroup on E-Pedigree

1. Discussion of Proposed Comments for FDA's Proposed Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification of Prescription Drug Packages
2. Discussion of Comments for FDA's Proposed Guidance for Industry on Unique Device Identification Systems
3. Discussion and Updates to Implement Electronic Pedigree Requirements -- Presentations by:
   - Federal Food and Drug Administration
   - Congressmember Buyer's Office
   - GS1
   - Oracle
   - Other Interested Manufacturers, Wholesalers, Pharmacies and Their Associations

B. Enforcement Committee

1. Discussion of Policies Involving Home Generated Pharmaceutical Waste Take Back by Pharmacies
   - Model Guidelines for Home Generated Pharmaceutical Waste Approved by the California Integrated Waste Management Board (February 2009)
   - Senate Bill 26 (Simitian)

Agenda Continues on Second Page

- Comments Sought by the Federal Drug Enforcement Administration on Disposal of Controlled Substances by Persons Not Registered with the DEA – Docket No. DEA-316 A

2. Update on Activities to Implement E-Prescribing in California
3. California's Controlled Substance Utilization Review and Evaluation System (CURES), a presentation and question and answer session led by Department of Justice, Bureau of Narcotics Enforcement
   - Implementation Issues Surrounding the New Data Collection Vendor for CURES
   - Moving to Provide Online, Near Real Time Reports to Practitioners on Controlled Substances Dispensed to Patients by July 1, 2009
5. Update Regarding Arrests and Criminal Convictions of Board Applicants and Licensees
6. Department of Consumer Affairs' Policies Regarding Pursuit of Interim Suspension Orders Discussion
7. Public Comment for Items Not on the Agenda*

* *(Note: the committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Adjournment

Note: Adjournment time is approximate ***4:00 p.m.***

Meeting materials will be available from the board's Web site by March 6, 2009

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: March 5, 2009

To: Enforcement Committee

Subject: Workgroup on E-Pedigree

At this meeting, the Enforcement Committee will convene a Workgroup on E-Pedigree Meeting. Future meetings of the workgroup will be convened as necessary; at present, the plan is to host such meetings once or twice a year for the next few years.

Background:
The 2008 Legislative Session ended September 30, which is the date when the Governor signed SB 1307(Ridley-Thomas). This law now staggers implementation of e-pedigree requirements in California away from 2011 to:

- 50 percent of a manufacturer's products by 2015
- the remaining 50 percent of the manufacturer's products by 2016
- Wholesalers and repackagers must accept and pass e-pedigrees by July 1, 2016, and
- Pharmacies and pharmacy distribution centers must accept e-pedigrees by July 1, 2017

There is preemption language that would repeal California's provisions if federal law regarding e-pedigrees is enacted, or if federal standards are enacted, they would take effect in CA.

There are provisions that define drop shipments, 3PLs, repackagers and manufacturers. Grandfathering provisions for drugs already in the supply chain are included.

The board will ultimately have to develop regulations for various components, including inference. No action on these regulations is planned for several years.

Agenda Item A.1:
The committee will have an opportunity to discuss the FDA's request for comments on "Draft Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification for Prescription Drug Packages" (**Attachment 1**). These comments are due April 16, 2009.

Under 2007 federal law (Federal Food and Drug Administration Amendments Act of 2007 (FDAAA)), the FDA was charged to develop a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing "sufficient to facilitate the

identification, validation, authentication, and tracking and tracing of the prescription drug." This would be the serialized identifier referenced in California's e-pedigree law.

At this meeting, the Workgroup on E-Pedigree will have the opportunity to discuss this request for comments and determine whether the board should submit comments in support of the FDA's identification of this identifier. Also, since the FDA will be attending this meeting, the Workgroup on E-Pedigree will be able to ask questions of the FDA regarding this process.

As a reference, **Attachment 2** contains the comments made by the board in 2008 in response to the FDA's initial request for comments on this topic.

Agenda Item A.2:

For information: on February 12, 2009, the FDA convened a hearing on "Unique Device Identification System" (**Attachment 3**). This hearing was convened to enable the FDA eventually to "promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary [of HHS] requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

While California's e-pedigree requirements exclude dangerous devices, the board still regulates the distribution of dangerous devices within, throughout and into California.

This issue is provided for your information and discussion.

Agenda Item A.3:

The board has received interest from several individuals willing to present information about the status of pedigree laws and regulations nationally.
At this meeting, there will be scheduled presentations by:

- FDA
- Congressman Buyer's Office
- GS1
- Oracle

Time has also been set aside for others in the audience to provide information to the Workgroup on E-Pedigree. There is no formal sign up for these presentations; this portion of the agenda is intended to provide for a full exchange of information from interested parties.

Additionally, staff seek comments from attendees on how they would like future Workgroup Meetings to be structured, and what guidance they seek from the board in these meetings in the future.

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STATE AND CONSUMERS AFFAIRS AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **March 5, 2009**

To: **Enforcement Committee**

Subject: **Update on Take-Back Drug Programs in Pharmacies**
Agenda Item B1

Background:
Last year, SB 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated Waste Management Board to develop the parameters for "model" drug take-back programs in pharmacies (a copy of this law follows). These model programs are intended to provide consumers with the ability to dispose of unwanted prescription and OTC drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage. Under SB 966, these guidelines were to be in place by December 2008.

State and federal law regulates prescription medicine until it is dispensed to patients. It is not regulated again unless it is collected at consolidated points, at which point it becomes medical waste, and must be handled and destroyed in specific, mandated ways.

Patients are often confounded about what to do with unwanted medicine. Californians are increasingly wanting "green" options for disposing of unwanted medicine, which current law does not allow. There is no viable process, other than to make the discarded drug products unpalatable (mixing with kitty litter or other substance, wrapping in duct tape, etc.) and then placing them in the trash. Some drugs may be flushed down the toilet, and are specifically labeled by the manufacturer to dispose of in this manner.

Pharmacies have in some cases agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not authorized in law.

Some communities periodically offer community take-back events, or special days at landfills where the public can take back drugs.

Some drug manufacturers (and the state of Maine, where there is a pilot program underway) provide mailers that patients can use to send unwanted medicine to a predetermined location for destruction. This is the process preferred by the DEA for controlled drugs.

The greatest problem for the board with drug take-back programs is the potential for these drugs to be diverted to the streets. There is a serious prescription drug abuse

problem in the US, and the uncontrolled aggregation of prescription medicine is an attractive enticement. In some cases, drugs collected in collection bins could re-enter the prescription drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain.

Pharmacies are areas where health care is provided – concern has been expressed that it is difficult for this purpose to be combined with a recycling center, where high sanitation is not necessarily a priority.

Pharmacies also have expressed concern that they may be required to absorb the costs of paying for disposal of these returned drugs, for sorting out controlled drugs (which potentially would require a pharmacist's time) and for assuring the safety and periodic emptying of collection bins.

Update for this meeting:

Item 1:
At the January 2009 and October 2008 Board Meetings, the board discussed concern with the proposed model program guidelines as drafted by the California Integrated Waste Management Board. However, the board did express its support for such programs on a voluntary basis with appropriate, specified safeguards.

Executive Officer Herold provided the board's concerns with provisions in the draft model program guidelines at a committee meeting of the Integrated Waste Management Board (CIWMB) on November 10.

On November 13, the CIMWB adopted the Model Guidelines, without incorporating the additional changes listed in the board's November letter. However, a number of other entities also provided comments to guidelines. For this reason, the CIWMB agreed to consider modifications to the Model Guidelines at its February 2009 meeting.

Ms. Herold again provided written comments and testified to the CIWMB on February 18 (**Attachment 4**). Also provided in this tab section are comments from the California Department of Public Health, and the final adopted model guidelines of the CIWMB.

Item 2:
Additionally, Senator Simitian has introduced SB 26 (**Attachment 5**), which would direct the board to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop sustainable efficient policies to manage pharmaceutical wastes and the disposal of devices.

Item 3:
Finally, underlying what is a national problem about how to deal with unwanted and unused drugs, the Drug Enforcement Administration is currently seeking comments on "Disposal of Controlled Substances by Persons Not Registered with the Drug

Enforcement Administration" (**Attachment 6**). Comments for this item are due March 23, 2009.

Controlled Drugs are the one item that cannot be returned to pharmacies or to community take back events. Instead, only law enforcement can accept these items. The involvement of the DEA in establishing policy in this area is another indicator of the movement underway to provide green methods of disposing of unwanted pharmaceuticals.

The board may wish to provide comments to the DEA for this topic.

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Date: **March 5, 2009**

To: **Enforcement Committee**

Subject: **E-Prescribing Update**

A number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing. A principal reason is that statistics indicate that medication errors cost the health care system $77 billion and cause 7,000 deaths annually. A number of these errors could be prevented by full implementation of e-prescribing. Other savings have been projected from redirected time currently spent by prescribers and pharmacies in verifying and switching prescription orders.

By the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. Since then, various provisions have been added or amended to keep law supportive of allowing electronic prescriptions. A current deterrent is that controlled substances cannot be e-prescribed

On November 20, 2008, the Board of Pharmacy hosted an e-prescribing forum in conjunction with the Department of Consumer Affairs' Professionals Achieving Consumer Trust Summit. Other healing arts boards whose licensees prescribe drugs attended this forum as did our stakeholders and public interest groups. The Dental Board and Medical Board joined us as partners.

Also, the California HealthCare Foundation (CHCF) is strongly advocating adoption of e-prescribing. It also hosted a November 20 forum in San Francisco on e-prescribing.

Since then and among other projects, the CHCF has been working with the executive staff of the Medical Board and the Board of Pharmacy to host in the near future a series of statewide events where physicians and pharmacists could earn CE and simultaneously work through issues limiting adoption of e-prescribing. The CHCF is currently in the discussion phase and hope to have a "road show" they can take throughout California in the next few months.

The board has been asked if it is interested in participating and if so, if the board will grant CE to pharmacists who attend these events. The Medical Board has already agreed to do this.

The Enforcement Committee needs to determine if it wishes to recommend this project to the board.

Additionally Assembly Bill 718 has been introduced to require all prescribers and pharmacies to have the ability to transmit and receive prescriptions by electronic data transmission. This bill is provided in (**Attachment 7**). The sponsor of this bill is a technology firm, Reed Elsevier, Inc.

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Date: **March 5, 2009**

To: **Enforcement Committee**

Subject: **New Data Collection Vendor Secured for the Controlled Substances Utilization Review and Evaluation System (CURES) Effective January 1, 2009**

B. FOR INFORMATION:

In mid December, the board and California pharmacies were advised that effective January 1, 2009, the California Department of Justice would have a new data collection vendor for CURES, and that all California pharmacies were to submit data to this new vendor beginning January 1 (**Attachment 8**). This was a short transition, and we have learned that some pharmacies are having transmission issues.

The California Department of Justice is attending this meeting and is making it available to hear and resolve issues involving the transition to the new vendor.

Also, the DOJ will be providing the committee with an overview of the forthcoming online, real time reports that will be available to practitioners on controlled substances dispensed to patients by July 1, 2009.

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Date: **March 5, 2009**

To: **Enforcement Committee**

Subject: **Update Regarding Arrest and Criminal Convictions of Board Applicants and Licensees**

The public and board licensees expect the board to act to remove from practice or deny licensure to those with substantially related convictions.

As part of the board's regulatory process, the board requires fingerprint background checks on all applicants. In addition, the board recently implemented a change to the renewal forms for all individual licensees requiring self-certification of criminal convictions or discipline imposed by other regulatory agencies as part of the renewal process.

In recent years the board has become inundated with fingerprint results. Whereas in 2000/01 the board received 608 arrest and conviction notifications, in 2007/08 the board received over 3,000. Additionally, about 30% of individual renewal applicants fail to complete the self-certification on the renewal form.

When it became clear that the board could not address this increased workload with existing resources, the board submitted a request to increase board staff through the Budget Change Proposal process. Board staff was recently advised that our request to establish a criminal conviction unit was approved and included in the governor's budget. This unit will consisted of 6.5 positions and will be responsible for completing investigations on applicants and licensees who are either arrested and/or convicted of a crime and to determine if the arrest or conviction is substantially related to the duties and functions of the license obtained and therefore warrants action by the board.

We have begun recruitment to fill some of these positions; however will not be able to fully staff this unit until July 2009, when the board's budget will be augmented to fully fund the unit.

More recently, SB 389 (Negrete McLeod) was introduced. This legislative proposal requires all specified agencies, including the board, to require state and federal level criminal background checks for all applicants as well require all licensees who have not previously undergone state and federal criminal background checks, to complete that as a condition of renewal.

A copy of SB 389 (Negrete McLeod) is provided in Attachment 9.

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Date: **March 5, 2009**

To: **Enforcement Committee**

Subject: **Department of Consumer Affairs' Policies Regarding Pursuit of Interim Suspension Orders Discussion**

On December 15, 2008, the Deputy Director of Legal Affairs Doreathea Johson for the department issued a memo reiterating the department's policy to encourage the practice of licensing agencies to use Interim Suspension Orders (ISO) and PC 23s when the conduct of a licensee is such that the board cannot afford to wait for the completion of the administrative process, before taking action to ensure the safety of the public. This memo directs all DCA licensing agencies to institute procedures for ordering interim suspension orders as warranted as well as to make recommendations regarding specific conditions when the agency shall pursue a suspension via a PC 23. The memo further provides suggested parameters.

The board uses all legal actions authorized, including both ISOs and PC 23s when a case is egregious and immediate public harm is eminent. With the implementation of the Criminal Conviction Unit we anticipate an increase in the number of such actions as the board will have sufficient resources to more promptly address violations that warrant immediate suspension.

A copy of the memo is provided in Attachment 10.

Attachment 1

Draft Guidance for Industry on Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages

Docket No. FDA-2009-D-0001

studies. In coordination with the Office of Planning, Research and Evaluation, DPPE coordinates ANA's performance goals.

Dated: January 9, 2009.

Daniel C. Schneider,

Acting Assistant Secretary for Children and Families.

[FR Doc. E9–983 Filed 1–15–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0001]

Draft Guidance for Industry on Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages." This draft guidance is being issued under the Federal Food, Drug, and Cosmetic Act (the act), which requires FDA to develop standardized numerical identifiers for prescription drugs. We are also requesting responses from interested stakeholders to questions posed in this **Federal Register** notice related to the draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 16, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Ilisa B.G. Bernstein, Office of the Commissioner/Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4840, e-mail: *ilisa.bernstein@fda.hhs.gov*;

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210, e-mail: *Stephen.ripley@fda.hhs.gov*;

Jennifer Devine, Center for Drug Evaluation and Research, 10903 New Hampshire Ave.,Silver Spring, MD 20993–0002, 301–796–3347, e-mail: *Jennifer.devine@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Draft Guidance for Industry on Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages." On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) was signed into law. Section 913 of this legislation created section 505D of the act, which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Section 505D of the act directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication, and tracking and tracing of prescription drugs. No later than 30 months after the date of enactment of FDAAA, the statute also directs the Secretary to develop a standardized numerical identifier (SNI) to be applied to a prescription drug at the point of manufacturing and repackaging at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug. An SNI applied at the point of repackaging is to be linked to the SNI applied at the point of manufacturing, and to the extent practicable, the SNI should be harmonized with international consensus standards for such an identifier. (See section 505D(b)(2) of the act.) The provisions in section 505D(b) of the act complement and build on FDA's longstanding efforts to further secure the U.S. drug supply.

FDA sought public comment on specific questions related to development of an SNI. We received 59 comments from a range of stakeholders including manufacturers, wholesalers, pharmacies, trade and health professional organizations, technology vendors, health professionals, consumers, and state governments. The standards included in this draft guidance are based on information received in response to our request for comment and the agency's familiarity with identification standards already in use for certain prescription biologics.

This draft guidance addresses only package-level SNI. Linking of a repackager SNI to a manufacturer SNI is not addressed in this guidance. Additionally, standards for track and trace, authentication, and validation are not included in this guidance. This draft guidance is intended to be the first of several guidances and regulations that FDA may issue to implement section 505D of the act; issuance of this guidance is intended to assist with the development of standards and systems for identification, authentication, and tracking and tracing of prescription drugs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on Standards for Drug Supply Chain Security—Standardized Numerical Identification for Prescription Drug Packages. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Request for Information

To assist us in finalizing the draft guidance and aid us in future guidance development and rulemaking related to section 505D of the act, we are seeking responses from interested stakeholders on the following questions. We also

welcome comment on any aspect of the draft guidance.

1. We believe that the serialized National Drug Code (sNDC) described in the draft guidance is appropriate for package level identification for most prescription drugs; however, it might not be useful at the pallet or other intermediate level, such as the case. We did not receive many comments related to standards for numerical identification at the case or pallet level and would like broader input on this subject. Please comment on whether there are any standards that would be appropriate for serialization or other numerical identification at the case or pallet level.

2. Some comments recommended that the SNI allow for alpha-numeric serial numbers in order to increase the choices for the numbers. FDA's draft guidance recommends that the SNI for most prescription drug packages be an sNDC, consisting of the NDC plus a unique 8-digit numerical serial number. Given the FDA recommendation for SNI, please comment on the necessity of having the serial number allow for alpha-numeric possibilities and under what standards this might be achieved.

3. Blood and blood components currently use either the ISBT 128 standard or Codabar for product package identification. In addition, hematopoietic stem cells derived from peripheral and cord blood use the ISBT 128 standard for product package identification. Please comment on whether these standards should be designated as the SNI for such products.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm,* or *http://www.regulations.gov.*

Dated: January 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–833 Filed 1–15–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0659]

Draft Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated January 2009. The draft guidance document provides establishments that manufacture HCT/Ps with recommendations for complying with CGTP requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 16, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated January 2009. This guidance provides establishments that manufacture HCT/Ps with recommendations for complying with CGTP requirements under part 1271 (21 CFR Part 1271), subpart D (Current Good Tissue Practice), and requirements under part 1271, subpart E (Additional Requirements for Establishments Described in § 1271.10). This guidance also addresses whether the establishment registration and HCT/P listing requirements under part 1271, subparts A and B apply in certain instances.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 1271, subparts D and E, and §§ 1271.10 and 1271.21 have been approved under OMB Control No. 0910–0543.

Guidance for Industry

Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (OC) Office of Policy, Ilisa Bernstein at 301-796-4830; (CDER) Office of Compliance, Jennifer Devine at 301-796-344 , or (CBER) Stephen Ripley at 301-827-6210.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)
January 2009
Procedural

FDA-2009-D-0001

GDL

Guidance for Industry

Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages

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U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Center for Drug Evaluation and Research
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January 2009
Procedural

Contains Nonbinding Recommendations

Draft — Not for Implementation

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Guidance for Industry[1]

Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to address provisions set forth in Section 505D of the Federal Food, Drug, and Cosmetic Act (the act) regarding development of standardized numerical identifiers (SNIs) for prescription drug packages. In this guidance, FDA is identifying package-level SNIs, as an initial step to facilitating other measures for securing the drug supply chain.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Office of the Commissioner (OC), the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

II. BACKGROUND

A. Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act (the act), which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Section 505D directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication, and tracking and tracing of prescription drugs. No later than 30 months after the date of enactment of FDAAA, the statute also directs the Secretary to develop an SNI to be applied to a prescription drug at the point of manufacturing and repackaging at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug. An SNI applied at the point of repackaging is to be linked to the SNI applied at the point of manufacturing, and to the extent practicable, the SNI should be harmonized with international consensus standards for such an identifier. (See Section 505D(b)(2).) The provisions in section 505D(b) of the act complement and build on FDA's longstanding efforts to further secure the U.S. drug supply.

FDA sought public comment on specific questions related to development of an SNI by opening a docket to receive information. 73 FR14988 (March 20, 2008). We also shared this request with State governments, other Federal agencies, and with foreign governments. We received 59

comments from a range of stakeholders, including manufacturers, wholesalers, pharmacies, trade and health professional organizations, technology vendors, health professionals, consumers, and state governments. The standards included in this guidance are based on information received in response to our request for comment and the agency's familiarity with identification standards already in use for certain prescription biologics.

B. Scope of this Guidance

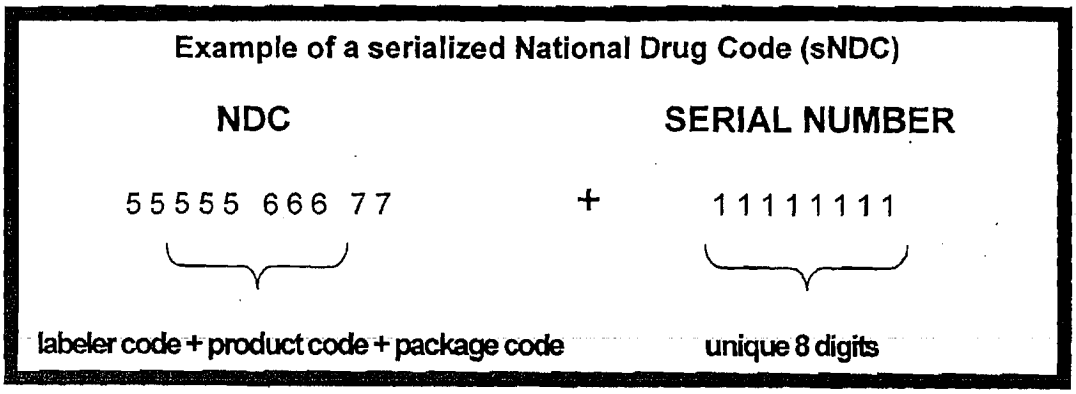
This guidance addresses only package-level SNI. For this purpose, FDA considers the package to be the smallest saleable unit placed into interstate commerce by the manufacturer or the repackager for sale to the pharmacy or other dispenser of the drug product. Standards for prescription drug SNI for the pallet level or other intermediate levels, such as cases, are not included in this guidance. Linking of a repackager SNI to a manufacturer SNI is also not addressed in this guidance. Additionally, standards for track and trace, authentication, and validation are not included in this guidance. This guidance is intended to be the first of several guidances and regulations that FDA may issue to implement section 505D of the act; issuance of this guidance is intended to assist with the development of standards and systems for identification, authentication, and tracking and tracing of prescription drugs.

III. STANDARDIZED NUMERICAL IDENTIFIERS

A. What should be designated as a package-level SNI?

Although manufacturers and repackagers are not required to use an SNI, for those manufacturers and repackagers who do, the SNI for most prescription drug packages should be a serialized National Drug Code (sNDC). The sNDC is composed of the National Drug Code (NDC) (as set

forth in 21 CFR Part 207)[2] that reflects each corresponding manufacturer or repackager, combined with a unique 8-digit numerical serial number generated by the manufacturer or repackager for each individual package. An example is shown below with a 10-digit NDC.



FDA recognizes that some prescription drugs approved under Section 351 of the Public Health Service Act, such as blood and blood components, do not use NDC numbers. Instead, such products currently use other recognized consensus standards for identification and labeling, e.g. ISBT 128 (see http://iccbba.org/about_gettoknowisbt128.html, and Guidance for Industry: Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels (http://www.fda.gov/cber/gdlns/unilabbld.htm) or Codabar. In addition, hematopoietic stem cells derived from peripheral and cord blood use the ISBT 128 standard for product package identification. Using these standards, a unique identification number is created for each individual product package. Therefore, for such products that do not use NDC numbers, FDA is considering use of ISBT 128 or Codabar as the SNI.

B. Does the SNI include expiration date and/or lot or batch number?

[2] Use of the sNDC as SNI is consistent with both existing provisions of part 207 and with FDA's proposed amendments to that provision, which would affect the assignment of NDCs. See 71 FR 51276 (August 29, 2006).

Expiration date and/or lot or batch number are not part of the SNI. Addition of this information within the SNI will increase the length of, and introduce complexity into, the SNI. Expiration date and/or lot or batch number are already readily accessible because FDA regulations require this information to be included on the label of each drug product. (See 21 CFR §§ 201.17, 201.18, 211.130, 211.137, 610.60, and 610.61.) However, if a manufacturer or repackager chooses to include expiration date and/or lot or batch number with the SNI, it should ensure that the resulting number still permits users to distinguish and make use of the SNI. For example, expiration date and lot or batch number may be incorporated in accordance with the GS1 standards for use of Global Trade Item Numbers (GTIN)[3] (discussed below).

C. Why did FDA select the serialized NDC for package-level SNI?

FDA chose the sNDC because we believe that it serves the needs of the drug supply chain as a means of identifying individual prescription drug packages. That identification can in turn facilitate authentication and tracking and tracing of the prescription drugs. Because the sNDC incorporates an 8-digit numerical serial number with the NDC, it should provide appropriate robustness to support billions of units of marketed products without duplication of an SNI. This approach will allow manufacturers and repackagers to assign serial numbers to combine with the NDC for unique identification of individual product packages. The SNI can also be linked to other identifiers used for manufacturing and shipping purposes. As already noted, defining the SNI is expected to be a first step to facilitate the development of other standards and systems for securing the drug supply chain. Many aspects of the implementation of package-level SNI will take shape in the future, as the standards that make use of SNI are developed.

[3] See www.GS1.org -- Healthcare GTIN Allocation Rules (http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf).

117

118 At this time, FDA is not specifying a particular means of incorporating the SNI onto the package.
119 The SNI identified in this guidance is compatible with, and flexible for, encoding into a variety
120 of machine readable forms of data carriers, such as 2-dimensional bar codes and RFID,[4] leaving
121 options open as technologies useful for securing the supply chain continue to be identified, and
122 standards making use of SNI are developed. FDA expects that SNI generally will be applied to
123 each package in both human readable and machine readable forms. A redundant human readable
124 SNI on the package will provide the ability to identify the package when electronic means are
125 unavailable (e.g., in the event of hardware/software failure). FDA also is not specifying a
126 location on the package where an SNI should be placed, although any SNI would need to be
127 placed on the package in a manner that does not obstruct FDA required labeling information.

128

129 In addition to facilitating other actions to secure the drug supply chain, adoption of the sNDC as
130 the SNI satisfies the requirement in 505D(b)(2) that the SNI developed by FDA be harmonized,
131 to the extent practicable, with international standards for such an identifier.[5] Specifically, use of
132 sNDC is compatible with, and may be presented within, a serialized Global Trade Item Number
133 (serialized GTIN or sGTIN). GTIN is a global standard for item and object identification,
134 established by GS1, a consensus-based, not-for-profit, international standards organization that
135 works with manufacturers, distributors, retailers, and others in the drug supply chain. FDA has
136 been an active observer and participant in GS1 standards development related to healthcare and

[4] FDA's enforcement policy with respect to the application of current good manufacturing practices to RFID technology is provided in Compliance Policy Guide (CPG) Section 400.210. See http://www.fda.gov/oc/initiatives/counterfeit/rfid_cpg.html. This CPG would apply if an SNI were embedded into an RFID tag.

[5] The potential alternative SNI for blood and certain other biologics identified above also use international consensus standards (ISBT 128).

drug products. According to documentation from GS1, the GTIN is used worldwide by twenty-three industry sectors, including healthcare, and has been adopted by sixty-five countries to uniquely identify pharmaceutical products. A GTIN may be used to uniquely identify items at the package level throughout the supply chain; combining a serial number with the GTIN ("serializing") results in an sGTIN that is unique to the individual package.

PC PHARMACEUTICAL COMMERCE

FDA PROPOSES 'SERIALIZED NDC' CODES FOR ITEM-LEVEL PHARMACEUTICAL PACKAGING

Agency follows through on steps toward a national standard for anticounterfeiting and product tracking

Give FDA's Office of Regulatory Affairs credit for keeping to a timetable for meeting a requirement of the FDA Amendments Act of 2007 (FDAAA): The agency has published draft guidelines to meet Section 913 of that law, by which Congress ordered the agency to "develop standards for identification, validation, authentication and tracking and tracing of prescription drugs." To that end, FDA held a public comment period last spring to solicit recommendations. Now, it has issued a proposed "Guidance for Industry" on one part of that mandate—the choice of a serialization system, to be called "serialized NDC" (sNDC), and is inviting comments through the next 90 days.

By itself, sNDC is fairly innocuous: FDA is recommending combining existing National Drug Code (NDC) numbers, which have 10 digits, with a unique eight-digit number, resulting in the 18-digit sNDC. The sNDC could then be incorporated into a barcode label, possibly with a human-readable code alongside it. The code is defined only for item-level packages, not cases or pallets, and this part of the Guidance does not cover tracking methods or authentication, which will presumably come later.

But behind the sNDC guidance is a much bigger goal: a national standard for encoding and tracking drug shipments, at the item level. This would replace (or at least align) the pedigree systems now in place in over half of the U.S. states. The lack of national uniformity has long been a complaint of industry and distributors since the pedigree systems began to come into force earlier this decade. A uniform serialization system, combined with track-and-trace IT communications, in fact subsumes pedigree systems and opens up many possibilities in more-efficient supply-chain processes.

GS1 alignment

One other notable element: Without explicitly stating so, the guidance implies an eventual compliance with the product coding and data structures of the international GS1 organization, whose GS1 Healthcare Group has been has been working on standardized systems for identifying products, locations and supply chain functions. "[U]se of sNDC is compatible with, and may be presented within, a serialized Global Trade Item Number"—which is part of the evolving GS1 structure, says FDA.

FDAAA orders FDA to develop a uniform serialization system for package- through pallet-level shipments, along with recommendations for validation and authentication processes, by March 2010. Meanwhile, various efforts to write a law specifying a tracking system, along with a schedule for implementing it, were part of the past Congress, and are expected to reappear in the new Congress.

Attachment 2

Previously Submitted Comments by the Board to "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication of Prescription Drugs"

Docket No. FDA-2008-N-0120

GMG

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

May 12, 2008

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: RESPONSE OF THE CALIFORNIA STATE BOARD OF PHARMACY
Docket No. FDA-2008-N-0120
Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments

To Whom It May Concern:

I write on behalf of the California State Board of Pharmacy. We are pleased to have this opportunity to respond to the Request for Comments included in Docket No. FDA-2008-N-0120, which has been titled "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments." We are encouraged by and support expeditious action by the FDA in this vital standards-setting endeavor.

Our Historical Perspective in California

As you may know, the Board is the agency within California primarily responsible for the enforcement of California's drug pedigree law, a mandated serialization, electronic pedigree, and track and trace system designed to enhance the security of the drug supply chain. The California pedigree law was first enacted in 2004, with an initial effective date of January 1, 2007, and then modified and extended in 2006 by additional legislation that pushed the effective date to January 1, 2009. Recently, the Board exercised authority delegated to it by the 2006 legislation to further extend the effective date for implementation of the pedigree requirements to January 1, 2011.

The Board and its staff thus have several years experience developing and implementing pedigree laws. Further, since 2005 the Board and its staff have engaged in extensive outreach to all segments of the drug supply chain on the California pedigree law. Over that time, the Board has been grateful to receive invaluable support from the FDA in those efforts, and for its law.

This FDA support for California's pedigree law has mirrored a historical commitment at the FDA, as expressed for example in the 2004 and 2006 Reports by the FDA's Counterfeit Drug Task Force, to the same principles captured in California's pedigree law: a drug supply chain in which security is enhanced by a *universal* electronic pedigree requirement with full-system track and trace, and mass serialization *at the unit level* with standardized unique numerical identifiers. Both the FDA and California prefer, and assume this system will utilize, RFID technology.

The development of industry standards to accomplish an interoperable infrastructure is a necessary step in the implementation of any pedigree requirement. Standards for a standardized numerical identifier and for a technology or technologies to carry these identifiers (data carriers) are especially crucial. We therefore welcome and are enthusiastic about the FDA's efforts.

Response to Request for Comments

The Board has also been pleased to observe over the last several years that much if not all of the baseline work that would be required for development and implementation of national and international consensus industry standards has already been accomplished, at least in part during the industry's response to the imposition of the California and Florida pedigree requirements. As you are no doubt aware, nearly all of that effort has been conducted by or under the guidance and with the assistance of GS1 and/or GS1 US and/or EPCglobal Inc., the various incarnations of the centralized, national and international, neutral, and non-profit, standards-setting organization.

We expect and assume that GS1/EPCglobal will submit its own response(s), and will not attempt to provide the level of detail and specificity we assume will be provided therein. Instead, we will limit our comments to some basic principles and preferences we have developed over the last several years based on the vast quantity and variety of information we have collected.

A. Standard Numerical Identifier

Under the aegis of GS1/EPCglobal, the industry has already completed all or nearly all of the necessary work on development and implementation of a standardized numerical identifier to be used to identify individual products (and cases and pallets) in the supply chain. The standard identifier already in use within the industry is the Global Trade Item Number (GTIN), developed by GS1/EPCglobal. The Board is not aware of any competing or alternative standard identifier.

The Board strongly encourages the FDA to adopt the GS1/EPCglobal standard identifier. The GTIN is already in use and approved by the FDA for marking pharmaceutical products via a linear bar code. It has utility and extensibility for use with all other data carriers, as well. It is in use on packaging already with a significant majority of U.S. drug manufacturers and distributors.

We will not respond individually to all of the sub-categories or questions included in this sub-part (A), as standards-setting organization(s), industry participants, and technology vendors are better able to do so. We will be generally satisfied with urging adoption of the GTIN, except to note a few comments responsive to the specific questions posed in the notice:

- With regard to whether the standard numerical identifier should contain recognizable characteristics such as the National Drug Code (NDC) Directory number as part of its sequence or should be purely random, we note that the GTIN has the capacity to, and presently does, include/incorporate the NDC number. Though we recognize that this may reduce the full interchangeability of GTINs internationally due to inclusion of a U.S.-only NDC number, several of the professional pharmacist members of the Board have expressed a preference for inclusion of an NDC number in standard identifier(s). So much of the present tracking, billing, and payment infrastructure in the U.S. uses NDC number as a reference point that a certain level of comfort has developed with use of this identifier, and failure to include the NDC number may cause confusion.

- With regard to whether the standard numerical identifier should be in more than one place (e.g., at both the package and pallet level), we believe that full track and trace/ pedigree capacity will require application of unique identifiers on *both* the individual item-level package *and* the case, pallet, or other aggregation. What is most crucial is that individual item-level (mass) serialization and application of unique identifiers be mandated by law; the application of identifiers to cases and pallets naturally follows.

- With regard to machine-readable versus human-readable, we feel strongly that it is of crucial importance to have machine-readable identifiers. Automatic data capture is an absolute necessity to preserve and extend the current processes and efficiencies in the drug supply chain. The fewer allowances that are made for human error the better. In fact, we also believe it critical to mandate or at least strongly encourage that standard numerical identifiers be encoded on carriers capable of non-line-of-sight data capture. This is the only means of transmission that is feasible for the entire supply chain.

- With regard to other questions posed under the "Characteristics" heading, we limit our comments to the observation that, as you have obviously realized, these are the kinds of decisions that must be made by industry consensus. In our view, there must be standards regarding whether or not to include a product type header/digit, how the parties in the supply chain ensure that numbers are unique and not duplicated, and/or whether or not the standard numerical identifier includes lot or batch number. What the particular decisions are with regard to those questions are of less concern to us.

- As for the "Standards" questions, we simply repeat our recommendation that the FDA strongly consider adoption of the GTIN as the pharmaceutical industry standard. The GTIN already enjoys that status within the industry, enjoying widespread adoption in the U.S. and internationally. There is no need to re-create this development process. We particularly encourage adoption of the SGTIN-96, which is the version applicable to serialization of drug products using RFID tag technology as the data carrier.

- And finally, with regard to the "Economic Impact" and/or "Harmonization with Other Countries" questions, we will again largely leave those to others to answer. However, we do observe that the economic impact(s) of universal item-level (mass) application of standard numerical identifiers, whatever they might be, are more than balanced by the dramatic impact on public health and safety this technology standard promises. A secure supply chain depends on an ability to reliably track and trace drug products, to prevent infiltration of counterfeit, misbranded, and/or adulterated products. And as is evidenced by the recent experience with Heparin, an effective recall also depends on a serialized-to-the-unit-level drug supply, that is absent now. Unit-level serialization will also bring the U.S. supply chain *more* in line with international standards, as it is much more the practice in other countries to have patient-level serialization (as well as packaging). It is high time that the U.S. employed a similar practice standard.

B. Standards for Validation

We are not sure what is meant by use of the terms "Standards for Validation." This is not a terminology we are accustomed to hearing, nor does it appear to clearly relate to any particular standard(s) or industry practice(s) we have encountered over the last several years.

To our knowledge, no such particular, specific "standards" for "validation of prescription drugs" presently exist, aside from those standards, practices and procedures developed to ensure and enable compliance with legal requirements such as those mandated in California and Florida, like the GS1/EPCglobal Pedigree and EPCIS standards. These standards *include* provisions and allowances for validations of prescription drugs, but would probably not be said to *be* such.

C. Standards for Track and Trace

Likewise, we are not sure what is meant by "Standards for Track and Trace." This is not a terminology we are accustomed to hearing, nor does it appear to clearly relate to any particular standard(s) or industry practice(s) we have encountered over the last several years.

Again, to our knowledge, no such particular, specific "standards" for "track and trace of products in the supply chain, generally" presently exist, aside from those standards, practices and procedures developed to ensure and enable compliance with legal requirements such as those set by California and Florida, like the GS1/EPCglobal Pedigree and EPCIS standards. Each of these standards *include* provisions and allowances for, or *enable,* tracking and tracing of drugs.

D. Standards for Authentication

And finally, we are also not sure what is meant by "Standards for Authentication." This is also not a terminology we are accustomed to hearing, nor does it appear to clearly relate to any particular standard(s) or industry practice(s) we have encountered over the last several years.

Again, to our knowledge, no such particular, specific "standards" for "authentication of products in the supply chain, generally" presently exist, aside from those standards, practices and procedures developed to ensure and enable compliance with legal requirements such as those set by California and Florida, like the GS1/EPCglobal Pedigree and EPCIS standards. Each of these standards *include* provisions and allowances for, or *enable,* authentication of drug products.

E. Prioritization

What is clear to us, and requires no clarification, is that the highest priorities for the FDA, in this invaluable standards-setting venture, ought to be *immediate* and *concurrent* development of two standards: (1) the specification(s) for the standard numerical identifier to be placed on the item-level (and case- or pallet-level) packaging for prescription drugs; and (2) the standard(s) for the data carrier(s) that should be used to encode and affix those numerical identifiers.

As we have stated in our separate submission in response to the accompanying Docket on the specific subject of promising technologies, we believe it is imperative that the FDA settle on RFID tags and technology as the mandated/preferred carrier. To do so, we hope the FDA takes a leadership role in also settling the question of propriety of use of RFID tags on biologic products.

The Board looks forward to continuing its historical cooperation with the FDA as it sets forth on this standards-setting endeavor. The Board is very hopeful that the FDA can move very quickly to establish these national standards, as the FDA has indicated is its intent by moving to expeditiously publish the pertinent Docket event(s) and request(s) for comments/information.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation's drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best route for contact is via Executive Officer Virginia Herold, at (916) 574-7911, or Virginia_Herold@dca.ca.gov.

Sincerely,

William Powers

WILLIAM POWERS
President, California State Board of Pharmacy

Attachment 3

Unique Device Identification System; Public Workshop; Request for Comments

Docket No. FDA 2008-N-0661

Trade Association." In this final guidance, FDA is announcing that: (1) We intend to proceed with a Certification Referral Program to NOAA SIP, without a 24-month test period, (2) we intend to expand the program to include all fish and fishery products for export to the EU and EFTA, and (3) we intend to stop issuing EU Export Certificates effective February 17, 2009. The agency intends to adopt this approach because the industry's demand for EU Export Certificates continues to rise dramatically, and FDA can no longer justify the use of our limited food safety resources for issuance of EU Export Certificates. The implementation of this guidance should free up resources that the agency can allocate for higher priority public health activities that are intended to protect the U.S. consuming public, while still providing a mechanism for the industry to continue obtaining EU certification. Seafood processors and other entities involved in the exporting of seafood to the EU may obtain EU Export Certificates from the NOAA SIP.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA, NOAA SIP, or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/guidance.html.*

Dated: January 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–785 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0661]

Unique Device Identification System; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: "Unique Device Identification System." The purpose of the public workshop is to obtain information to help us better understand the issues involved in the establishment of a unique device identification system (UDI system) and request comments on this topic.

Dates and Time: The public workshop will be held on, February 12, 2009; from 9 a.m. to 5 p.m. See section V of this document for additional dates associated with registration and participation in the workshop.

Location: The public workshop will be held at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878, 301–590–0044.

Contact Person: Jay Crowley, Food and Drug Administration, Center for Devices and Radiological Health (HFZ–500), 1350 Piccard Dr., Rockville, MD 20852, 240–276–2389, or Stephen Ripley, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

Registration: Register electronically at *http://www.fda.gov/cdrh/ocd/udi/index.html*by January 30, 2009. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Jay Crowley (see *Contact Person*) by January 30, 2009.

Comments: Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The deadline for submitting comments regarding this public workshop is February 27, 2009. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

A. What Does Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) Require?

On September 27, 2007, President George W. Bush signed into law FDAAA (Public Law 110–85). Section 226 of FDAAA amended the Federal Food, Drug, and Cosmetic Act (the act) by requiring the establishment of a UDI system. Specifically, section 226(a) of FDAAA created a new section 519(f) of the act (21 U.S.C. 360i(f)) stating that "The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

A UDI system may provide for early detection of the warning signs of a defective device and facilitate device recalls (Ref. 1) and other possible benefits of a UDI system have been suggested.

B. Why Are We Holding a Public Workshop?

The enactment of section 519(f) of the act has raised many questions for our consideration. For example, the statute requires the UDI to go on the device's label, but it also allows for "alternative placement" and for exceptions. Thus,

what circumstances would justify alternative placement of the UDI, and which devices should receive an exception from a UDI requirement? Consequently, we are issuing this notice to announce that we will hold a public workshop to discuss and to invite comment on the questions set out in section II. B of this document.

II. Issues to Be Considered

A. Organization and Basic Instructions

We invite comments on the questions presented in this section. We intend to discuss these same questions at the public workshop. If you wish to comment in writing on a particular question, please identify the question that you are addressing before providing your response to the question. For example, your comment could take the following format:

"Question 1—[Quote the question]."

"Response—[Insert your response]."

You do not have to address each question. Additionally, for those questions pertaining to economic issues or the prevalence of a particular problem or action, please provide data and/or references so that we may understand the basis for your comment, figures, and any assumptions that you used.

As this workshop will only take place over the course of a single day, in order to most effectively use this time and obtain as much information from as many diffferent points of view as possible, the public workshop will be divided into sessions that focus on each of the main topic areas. Each session will begin with an invited presentation to describe the issue. This will be followed by a moderated question and comment session. Following this discussion, the moderator will open up the discussion to questions and comments on the topic from the audience. Though limited, at the end of the day there will be time for other presentations.

Because of the workshop's format, we will only have a short time for additional presentations. We encourage attendees to raise their issues and concerns during the discussion portion of the main topic areas. We also encourage persons and groups having similar interests to consolidate their information and present it through a single representative.

Additionally, through this public workshop, we hope to gain greater understanding of various automatic identification technologies. Therefore, we invite manufacturers and organizations that market or have in development automatic identification technologies, which could be used with medical devices, to display these technologies. Questions about whether your product or technology would fall within the scope of this vendor display should be directed to the contact persons listed at the beginning of this notice.

You may register to present at the public workshop or participate in the vendor display at *http://www.fda.gov/cdrh/ocd/udi/index.html*. Because of time constraints, vendors may register either to present at the public workshop or participate in the vendor display. You may not register for both. If you choose to participate in the vendor display, you will have the opportunity to share information about your products with FDA and other attendees when they visit your display.

B. Questions Pertaining to the UDI System

1. Which types of devices or particular devices should be subject to the requirements of a UDI system? Which types of devices or particular devices should be excepted?

Section 519(f) of the act states that the Secretary of Health and Human Services may provide "an exception for a particular device or type of device." However, the statute does not specify any criteria for an exception, nor does it describe the scope of an exception.

a. Should all devices be subject to the requirements of a UDI system? Please explain your reasoning.

b. Are there types of devices or particular devices that should receive an exception from the requirements of a UDI system? If so, what types of devices or particular devices should receive an exception and why?

2. What are the characteristics or aspects necessary to uniquely identify a device?

Section 519(f) of the act states that the UDI "shall adequately identify the device through distribution and use, and may include information on the lot or serial number." The statutory language does not describe the characteristics or features that make a device "unique" or that "adequately identify the device through distribution and use."

a. What characteristics are needed to uniquely identify a device?

b. What core attributes, elements, or characteristics of a device should constitute a minimum data set for a device identifier?

c. What changes to an attribute, element, or characteristic associated with the unique identification of a device change should result in a new UDI?

d. Should the UDI include a component that represents package size or packaging level?

e. To what extent would or should the list of unique device characteristics vary depending on the type of device?

3. What should be the UDI's components?

a. Could existing standards, such as the standards used by GS1, Health Industry Business Communications Council (HIBCC), or others be used as a model for the UDI system? What are the advantages and disadvantages of these existing organizations and standards?

b. Some identification systems currently in use employ a combination of a device identifier (meaning information that identifies the manufacturer, make, and/or model of the device) and a production identifier (meaning information that relates to the lot or serial number). What should the device "identifier" component of the UDI cover or contain?

c. With respect to the production identifier, we note that the statute says that the UDI may include information on the device's lot or serial number. When should lot or serial number information be required for a device? Are there particular devices for which serial numbers should be required? If yes, what particular devices should be labeled with a serial number? Please explain your reasoning.

d. How might we ensure that UDIs, regardless of the manufacturers or devices associated with those UDIs, are uniform or standardized in their structure or composition? For example, the NDC (National Drug Code) number is always 10 digits long and always presents the labeler code first, followed by the product code and then the package code. Should we limit the number of ways that the UDI can be created or the standards to be used?

e. How should the UDI be created to ensure that UDIs are unique?

4. Where should the UDI be placed? What should be the criteria for alternative placement of the UDI?

The statute requires the label of devices to bear a unique identifier, unless we require an "alternative placement" or provide an exception. Section 201(k) of the act defines "label" "as a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the

outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

a. Should we specify where on the label the UDI must appear? If so, where should the UDI appear on the label? Please explain your reasoning.

i. Should we allow the components of the UDI to be placed separately on the same package or on different levels of packaging? For example, if the UDI consists of a device identifier component and a production identifier component, should we allow the device identifier component of the UDI to be placed in one location and allow the production identifier component to be placed elsewhere on the label or on the device? Please explain your reasoning.

As another example, some devices are packaged individually and then packaged again in a larger container (such as a "shelf pack"). We are aware that some manufacturers would prefer placing both the device identifier component of the UDI and the production identifier component of the UDI on the larger container and placing only the device identifier component of the UDI on the individual packages. Separating UDI components or allowing part (rather than all) of the UDI on package labels may provide for flexibility in product labeling, but also generate confusion as to which UDI to read or scan (if the UDI components are separated) or limit the usefulness of the UDI if a component of the UDI is not present.

ii. For barcodes (whether linear or two-dimensional (2D)), should we require the UDI to be expressed in a concatenated manner (whereby the components of the UDI are expressed on the same line adjacent to each other) or in a stacked manner (whereby one component of the UDI rests atop the other component)?

b. Are there devices where we should require the UDI to appear on the device itself (direct part marking)? For example, it might be beneficial to put the UDI on the device itself if the device is re-processed because this might help firms identify or record how many times a particular device has been reprocessed. Similarly, certain single use devices (SUDs) sometimes are reprocessed, so a UDI on the device itself could facilitate the mandatory and voluntary MedWatch reporting relating to such reprocessed devices or facilitate other activities (such as documenting sterilization reprocessing of SUDs and validation studies) associated with SUDs. Conversely, are there devices where the UDI cannot or should not go on the device itself? If so, please describe those devices and explain why the UDI cannot or should not go on the device.

c. If we allow for "alternative placement" of the UDI for some particular devices or types of devices, what should be the general criteria for requiring "alternative placement" of the UDI, e.g., such as on the device itself or other location that is not on the label?

d. What specific challenges or limitations exist regarding "alternative placement?" For example, placing a UDI in an automatic identification form on an implantable device may present issues as to whether the automatic identification technology affects the device's integrity or function. As another example, certain devices, such as software, may pose particular challenges for how to label with a UDI.

5. How should the UDI be presented?

We are aware of several automatic identification technologies in use, such as linear bar codes, 2D bar codes, and radio frequency identification. We also note that various FDA regulations and initiatives have required or recommended one or more automatic identification technologies (see 21 CFR 201.25 (bar code label requirement for human drug products); 21 CFR 610.67 (bar code label requirement for biological products); Ref. 2; and section 505D of the act (21 U.S.C. 355e) (regarding "pharmaceutical security" and specifying "promising technologies" such as RFID (radio-frequency identification), nanotechnology, encryption technologies, and other "track-and-trace or authentication technologies")). Therefore:

a. Should we require human-readable UDIs or automatic identification of UDIs or both? Are there devices where it would be sufficient to have human-readable UDIs alone? Please explain your reasoning. For example, devices used in a home care setting might not need an automatic identification UDI because the home might not be equipped to read the automatic identifier. Are there situations where we should require both human-readable and automatic identification UDIs? Please explain your reasoning.

b. Should we specify a particular type of automatic identification technology or should we allow the automatic identification technology to vary depending on the type of device? Should we identify automatic identification standards (as opposed to specific technologies) that can be used? Please explain your reasoning. Specifying a particular type of automatic identification technology would enable hospitals and other parties who might read or use a UDI to make specific investments in scanning or reading equipment, but the technology chosen might not be easily applied to all devices (if we require the UDI to be placed somewhere other than the label.) For this question, we are particularly interested in hearing from parties who might use UDIs as well as entities that may have already adopted or installed device identification systems.

c. Should we allow the use of different automatic identification technologies to express different parts of the UDI? For example, the device identifier component might be expressed in a linear bar code and the production identifier component might be expressed in a 2D bar code. Allowing the use of different technologies for different components of the UDI may enable manufacturers to make more efficient use of label space or space on the device itself, but it also could generate confusion as to which identifier to read or scan and could necessitate the purchase of several types of reading and scanning equipment.

d. Are there existing standards or systems we should consider in establishing the requirements for how the UDI must be presented? For example, we are aware of various standards organizations, such as GS1 and the HIBCC, that exist and have specific formats or specifications for automatic identifiers for products. Should we allow any or all of these standards to be used?

6. How should the UDI Database be developed and maintained?

For parties to benefit from UDI information, it would seem necessary for those parties to know, at a minimum, the UDIs that exist, the specific device associated with each UDI, and the information associated with each UDI. It might be efficient for one entity to collect the UDIs, associate those UDIs with specific devices, and make the information associated with those UDIs publicly available. However, it is also conceivable (but perhaps less efficient or more costly) that the information could rest with individual manufacturers themselves (rather than FDA) or with a third party or third parties. Consequently:

a. How and when should we require UDIs and associated information to be entered into a database? How frequently should we require changes to a UDI or to the information associated with or linked to a UDI to be reported?

b. Aside from information that is necessary to uniquely identify a device,

what other information (if any) should be part of a UDI system database or otherwise linked to the UDIs?

c. If variable data (such as a lot or serial number) is necessary to uniquely identify a device, should such data be included in a UDI system database?

C. Questions Pertaining to Possible Impacts of a UDI System

Many production situations that might be affected by UDI requirements are complex. In its basic form, a device identifier is a series of digits and/or letters associated with a specific device. At a minimum, a system can be thought of as the set of procedures that allow stakeholders to use an identifier. Through public consultation, however, FDA has found that there are many different views as to the purpose of a UDI system and different opinions about how to describe and implement a UDI system. Because of the diversity of affected devices and manufacturing processes, we expect that affected entities might comply with UDI requirements in a variety of ways. If you respond to the following questions about the costs and benefits of a UDI system, we encourage you to provide as much detail and context as possible. For example, if you identify exceptional costs related to incorporating a UDI in certain production lines, we need to understand the production process details. In addition, we specifically invite small businesses to provide information about a UDI's potential impact.

1. What is the magnitude of the problem to be addressed by the establishment of a UDI system?

Please describe and provide qualitative or quantitative evidence of the incidence of deaths, injuries and illnesses associated with medical devices. What role would a UDI system play in helping to reduce the incidence of such deaths, injuries, and illnesses and how might the structure of a UDI system facilitate this role?

2. Questions for manufacturers

a. *Current practices.* Describe your current practices for applying standards to medical devices, marking identifiers on medical device labeling and managing medical device identifier data. For example, how do you currently use classification standards such as UNSPSC (United Nations Standard Products Service Code), nomenclature standards such as GMDN (Global Medical Device Nomenclature), and identification standards such as GS1 or HIBCC? What percent of your devices are not currently marked with a standardized identifier? Please describe any plans you have to change these practices in the near future.

b. *Changing current identifiers.* If you were to add a UDI or change the presentation of your current identifier, please describe your approximate expected capital and operating costs (including labor) to plan for, implement, and apply a UDI to product labeling. To provide context for your estimate, please explain your expected approach to adding a UDI, considering the possibility that a UDI might be a static number (e.g., a manufacturer/product code) or that it might include a variable number (e.g., manufacturer/product/lot code).

c. *Encoding variable data.* If you were to add a UDI bar code with variable data (such as lot or serial number) to medical device labeling, please describe how you would print the variable bar coded information. For example, do you foresee using on-line label printing, other in-house printing, or contract printers to add a UDI bar code?

d. *Production line impacts.* Considering your operations, are there products where adding a UDI (human readable or barcode; static or variable) to labeling would not be feasible without major capital investment or overhauling production lines? If so, please describe the products and suggest alternatives or solutions.

e. *Small devices and small packages.* A UDI could present a challenge for some small packages. What percentage of your product line consists of devices whose small size could make placing a UDI on a label problematic? Of those devices identified, what "alternative placement" of the UDI would be feasible? Please explain your reasoning. Please describe the nature of the problems and costs to solve such problems. Please suggest alternatives or solutions.

3. Questions for hospitals, nursing homes, and clinics

a. *Using a UDI.* If UDIs were placed on at least some medical devices, what functions could a UDI serve in your institution?

b. *Expenses.* What expenses do you foresee in attempting to capture and use UDIs placed on medical devices? If you foresee using UDIs, how would you modify operations in your facility?

c. *Adverse event reporting and recalls.* How would capturing the UDI change your recall management or adverse event reporting? For recalls or adverse events involving the most serious device malfunctions or failures, how have problems in device identification impaired your recall management or adverse event reporting? Please describe the magnitude of the problems you have encountered.

III. References

The following references have been placed on display in the Division of Dockets Management (see *Comments*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. 153 Cong. Rec. H10597 (daily ed., September 19, 2007) (statement of Rep. Hooley).

2. FDA, "FDA Counterfeit Drug Task Force Report: 2006 Update," p. 12, (*http://www.fda.gov/oc/initiatives/counterfeit/report6_06.pdf*) (advocating use of RFID).

IV. Where and When Will the Public Workshop Occur?

We will hold the public workshop on February 12, 2009, from 9 a.m. to 5 p.m., at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

V. Do You Have To Register To Attend a Public Workshop or To Make a Presentation?

If you wish to make a presentation at or to attend the public workshop, please register online at *http://www.fda.gov/cdrh/ocd/udi/index.html* by January 30, 2009. The online registration form will instruct you as to the information you should provide. Space may be limited, and we will close on-site registration when the maximum seating capacity is reached.

We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations will depend on the number of people who wish to speak on a given topic, and the public workshop schedule. Similarly, the time allotted to each topic may vary depending on the expressed interests of persons registering for the public workshop. To obtain updates on the public workshop, please visit *http://www.fda.gov/cdrh/ocd/udi/index.html*. Additionally, regardless of whether you wish to make a presentation or simply attend the public workshop, if you need any special accommodations (such as wheelchair access or a sign language interpreter), please notify Jay Crowley (see *Contact Person*) by January 30, 2009.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be

accepted by FDA only through FDMS at *http://www.regulations.gov.*

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/cdrh/ocd/udi.index.html.*

Dated: January 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–784 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0656]

Secure Supply Chain Pilot Program; Notice of Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for sponsors and foreign manufacturers of finished drug products and active pharmaceutical ingredients (APIs) intended for human use imported by a secure supply chain to apply to participate in a voluntary Secure Supply Chain (SSC) pilot program to be conducted by FDA's Center for Drug Evaluation and Research (CDER) and Office of Regulatory Affairs (ORA). The goal of the pilot program is to allow FDA to determine the practicality of developing a secure supply chain program. The information obtained from this pilot program will assist FDA in its determination. A Secure Supply Chain program would assist the agency in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs by allowing the agency to focus its resources on imported drugs outside the program that may pose such risks. Such a program would increase the likelihood of expedited entry for specific finished drug products and APIs imported into the United States that meet the criteria for selection under the program.

DATES: Submit written or electronic comments on this pilot program by March 16, 2009. Submit written or electronic comments on the collection of information by March 16, 2009.

ADDRESSES: Submit written comments regarding this SSC pilot program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the collection of information to *http://www.regulations.gov.* All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kathleen Anderson, Office of Compliance, Division of New Drugs and Labeling Compliance, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 5182, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

The SSC pilot program is part of FDA's risk-based approach to regulating drug imports, and it follows the President's charge to the Interagency Working Group on Import Safety to better assure that imported products are safe.

The goal of the pilot program is to allow FDA to determine the practicality of developing a secure supply chain program. The information obtained from this pilot program will assist FDA in its determination. A Secure Supply Chain program would assist the agency in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs by allowing the agency to focus its resources on imported drugs that fall outside the program and that may pose such risks. Such a program would increase the likelihood of expedited entry for specific finished drug products and APIs imported into the United States that meet the criteria for selection under the program.

II. Definitions for the Purposes of This Program

- *Affirmation of Compliance (AofC) Code*: A code designated by FDA for use by filers to convey information related to product or firm compliance with agency requirements, used to help expedite entry processing. Some AofC codes require a qualifier to provide additional information to aid in expedited processing.
- *Automated Broker Interface (ABI)*: An integral part of the Automated Commercial System, ABI is the means by which brokers or importers transmit entry data to the U.S. Customs and Border Protection (CBP).
- *Automated Commercial System (ACS)*: The system used by CBP to track, control, and process all commercial goods imported into the United States.
- *Broker/Customs Broker/Filer*: A licensed Customs broker hired to file entries for another party or a Customs ABI participant that files its own entries.
- *Customs-Trade Partnership Against Terrorism (CTPAT)*: CTPAT is the CBP initiative that partners with members of the trade community on a voluntary basis to better secure the international product supply chain to the United States.
- *Foreign Shipper*: The firm identified or declared as the shipper at time of entry into the United States.
- *Importer of Record*: The person, establishment, or representative responsible for making entry of imported goods in accordance with all laws affecting such importation.
- *"May Proceed"*: This term means that an FDA-regulated imported product may proceed into domestic commerce after the electronic screening. This is not a decision by FDA about the product's regulatory status, and it does not preclude FDA action at a later time.
- *Manufacturer ID (MID)*: Manufacturer identification code constructed with specific segments of the manufacturer's or shipper's name and address. Refer to CBP Customs Directive Number 3550–055 (Old Number 3500–13), dated November 24, 1986, for instructions on determining the manufacturer ID.
- *Ultimate Consignee*: The party in the United States, at the time of entry or release, to whom the overseas shipper sold the imported merchandise. If at the time of entry the imported merchandise has not been sold, then the Ultimate Consignee at the time of entry or release is defined as the party in the United States to whom the overseas shipper consigned the imported merchandise.

III. SSC Pilot Program

A. Description

The SSC pilot program will be jointly administered by the Office of Compliance in CDER and the Division of Import Operations and Policy (DIOP) in ORA. To be selected to participate in the SSC pilot program, an application must meet the following criteria:

1. The applicant must submit a complete application, which is Form

Attachment 4

Comments on Model Guidelines for y Drug Take Back from Patients

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: California Integrated Waste Management Board

From: Virginia Herold, Executive Officer

Date: February 18, 2009

Subject: Model Guidelines for Home-Generated Pharmaceutical Waste
Agenda Item C

The California State Board of Pharmacy regulates those who ship, store, transport, sell and dispense prescription drugs to patients and practitioners in California, and ship prescription drugs and devices into, from and throughout California. We license approximately 6,600 pharmacies in California, 500 of which are hospital pharmacies. We license over 112,000 individuals and other businesses involved with prescription drug distribution.

Prescription drugs are tightly regulated down to the consumer level – the manufacturers are licensed, the wholesalers are licensed, the pharmacies are licensed, the practitioners who prescribe and sometimes dispense are licensed. However, once drugs are dispensed to the patient, there are no specified ways for the patient to destroy unwanted/unneeded drugs. Consumers often either toss them into the trash, or flush them down the toilet.

Prescription drugs are not regulated again unless they are aggregated, and then they become pharmaceutical or medical waste, and only licensed entities can handle this waste.

This regulation is important for a number of reasons. Foremost is to preserve the quality of our prescription medicine supply and the health of the public. Diversion of prescription drugs from highly regulated channels and prescription drug abuse are two reasons why aggregation and non-regulation of collection sites pose problems to society. However, the public is increasingly seeking green options for destruction of unwanted medicine.

For nearly one year, Board of Pharmacy staff has worked with a small working group of other state agencies, including the CIWMB, on the model programs. In November 2008, we provided comments on the proposed model program guidelines, and many of our recommendations have been incorporated into the guidelines before your board.

At this time, on behalf of the Board of Pharmacy, I wish to make the following statements:

1. The board remains greatly concerned with diversion of prescription drugs from these sites (whether in pharmacies themselves or at occasional community events) to pharmacies, where they will be re-dispensed to patients. Two such events have been highlighted in the media since November (where a pharmacy in Washington and a California physician were dispensing drugs acquired through a "take back" collection bin in their premises). Redispensing of medicine taken from collection bins is a serious threat to our drug supply and patient health. It

is also very difficult for regulators to identify such diversion. For this reason, we strongly assert that:

- Drugs should not be reviewed/received by staff at the collection site (whether a pharmacy or a community event) before being deposited into the collection device – the patients or patients' agents should do this themselves , and
- The drugs that are collected should be separated from their containers by patients or their agents before being placed in the containers.

This will aid in preventing diversion by pharmacy or collection site staff because no one is "reviewing" the drugs before they are placed in the container. Such practices will also reduce costs for disposal because the containers will not be part of the pharmaceutical waste. I am attaching a picture taken of a collection bin which shows the non-pharmaceutical material found in a bin.

2. Printed advertisements for community take back events should list who is responsible for the operation of the collection location, including the name, address, and phone number of the responsible party. All signage at collection sites should also clearly identify who is responsible for the collection operation.
3. Every operator of a model program must have written policies and procedures to document their operations and compliance with the guidelines.
4. At one-day or periodic events—we strongly advocate that the pharmaceutical waste must be picked up at the end of the day. It cannot be temporarily stored "for no longer than 90 days" (page 12 – top paragraph), and with permission for as long as one year. This conflicts with the more appropriate requirement that disposal occur on "the same day of the event" (page 13, item d).

I wish to note that on January 21, 2009, the Drug Enforcement Administration published in the Federal Register its intent to examine consumer disposal options for controlled substances. Whereas it appears that much of the DEA's interest lies in disposal of controlled substances from long-term care facilities, it is seeking comments from various designated entities including law enforcement agencies, publicly owned treatment works and pharmacies. These comments are due March 23.

We look forward to continuing to work on developing these programs so that they provide the public with the options they seek, and the safety and accountability needed to protect our prescription drug supply.

Thank you for your ongoing efforts in this area.

VIRGINIA HEROLD
Executive Officer

State of California—Health and Human Services Agency
California Department of Public Health

MARK B HORTON, MD, MSPH
Director

ARNOLD SCHWARZENEGGER
Governor

February 24, 2009

Ms. Margo Reid Brown, Chair and Board Members
California Integrated Waste Management Board
1001 I Street
Sacramento, CA 95814

RE: Comment to the "Revised Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs" dated February 24, 2009

Dear Madame Chair and Board Members,

We recently became aware that language modified in the SB 966 "Revised Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs" dated February 24, 2009 may contain misleading information for entities that use the guidance for their program. Under Section I on page 4, paragraph 5, "Signage" the statement "Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste" may lead readers to manage consolidated pharmaceuticals as "household wastes" and result in the improper management and disposal of these wastes. As noted on page 1, number 8 the Minimum Criteria for management of these wastes requires "consolidated" home generated pharmaceutical waste to be managed as medical or hazardous waste. This paragraph was added to comply with the California Health and Safety Code.

We suggest the following addition to the statement in paragraph 5 for each of the recommendations in "I. Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs" and "II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government-Sponsored One Time or Periodic Collection Events"

Medical Waste Management Program
P.O. Box 997377, MS 7405, 1616 Capitol Avenue, 2nd Floor, Sacramento, CA 95899-7377
(916) 449-5671 (916) 449-5665 Fax
Internet Address: www.cdph.ca.gov

5. **Signage ...** Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. *Wastes commingled in this manner must be handled as medical or hazardous waste.* ~~However, I~~ If home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction.

Thank you for you consideration regarding this latest comment. We appreciate the work that you and your staff have done to address this legislation.

Sincerely,

Kelvin Yamada, Chief
Medical Waste Management Program

Revised Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB) to develop model programs for the collection from consumers and proper disposal of unused or expired home-generated pharmaceuticals[1]. In developing model programs in California, the CIWMB is also required to evaluate programs used by other state, local, and other governmental entities. The CIWMB provided a survey to those entities that have collection programs and requested that they complete and return it to the CIWMB. The purpose of the survey was to acquire information on existing home-generated pharmaceutical waste collection programs in California. From the survey results, the Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs (Procedures) were developed that would help organizations or local governments create programs through which the public may return unused or expired home-generated pharmaceutical waste (typically a prescription drug dispensed to a consumer, or a non-prescription item, such as over the counter drugs, that are no longer wanted or needed by the consumer) and meet the following minimum criteria and goals of SB 966 and of the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health (CDPH), Board of Pharmacy, Department of Toxic Substances Control, and the State Water Resources Control Board).

The minimum criteria of SB 966 and of the Pharmaceutical Working Group for home-generated pharmaceutical waste collection model programs are as follows:

1. Requires, at no additional cost to the consumer, the safe and environmentally sound take back and disposal of unused or expired home-generated pharmaceuticals;
2. Ensures protection of the public's health and safety and the environment;
3. Ensures protection of the health and safety of consumers, and employees;
4. Report to the Board the amounts of home-generated pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability, and incidents of diversion of drugs for use or sale;
5. Protects against the potential for the diversion of drug waste for unlawful use or sale;
6. Provides notices and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
7. Subjects persons or businesses to consequences for failure to comply with model programs per SB 966 and related state and federal pharmaceutical and waste management statutes at the point of transportation, deposition, and consolidation;
8. Requires that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste must be managed as medical or hazardous waste. This would include all statutory requirements for storage and handling as medical or hazardous waste, the use of registered medical or hazardous waste haulers and approved treatment technology for disposal; and
9. Requires collection locations to have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.

Additional goals of SB 966 and the Pharmaceutical Working Group include:

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1 Throughout this document, the terms "home-generated pharmaceuticals" or "home-generated pharmaceutical waste" are used. Although the term does not appear in the law establishing this program, it is the term commonly used by stakeholders to refer to unused or expired pharmaceuticals in the possession of consumers.

1. ~~Provides~~ Providing for the collection of home-generated pharmaceuticals that is convenient for consumers;
2. ~~Maintains~~Maintaining privacy of all participants;
3. ~~Prevents~~Preventing the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;
4. ~~Ensures~~Ensuring that medication information is legible, so that it can be identified in case of a poisoning;
5. ~~Develops~~Developing a sustainable funding source for collection and disposal of home-generated pharmaceuticals, such as grants, utility funding; or advanced disposal fees placed on home-generated pharmaceuticals and local general funds or via extended producer responsibility funding framework.
6. ~~Strives~~Striving to develop permanent collection programs rather than one-day events, so they will be more accessible to the public; ~~and~~
7. ~~Provides~~Providing recommendations for implementation of a statewide program; and
8. ~~Recommends~~Recommending statutory changes to, for example, the Medical Waste Management Act.

The following Procedures have been extracted from both the Pharmaceutical Collection Programs Survey collection program information on the internet, and from the Pharmaceutical Working Group and are ~~required~~recommended for pharmaceutical collection programs. The Procedures are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used as a model to develop a collection and disposal program for unused/expired home-generated pharmaceuticals. The Procedures are broken down by (I) Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

I. Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs

As mentioned in the previous section on goals, it is preferable that permanent home-generated pharmaceutical collection programs be developed to provide the public with consistently accessible and convenient venues to drop off unused or expired home-generated pharmaceuticals. The following procedures are basic steps ~~that shall be taken~~ to implement permanent collection programs at these types of facilities.

1. **Types of Collection Facilities** – Only the following may maintain permanent collection locations for home-generated pharmaceuticals: pharmacies with active unrestricted licenses from the California State Board of Pharmacy, police and sheriff's stations, public/environmental health agencies, physician and other licensed health care prescribers' offices, Household Hazardous Waste (HHW) facilities, and healthcare collection sites. Healthcare collection sites are physical locations licensed or operated by individuals or entities licensed by an agency within the Department of Consumer Affairs (DCA), with these locations electing to collect or take-back home-generated pharmaceutical waste and/or sharps, as applicable. Examples of healthcare collection sites include but are not limited to physicians and surgeons' offices, dentists, veterinary offices and pharmacies. If a DCA licensee has their license revoked, suspended, placed on probation or otherwise limited in any way, it shall not operate a healthcare collection site. If collection is at a police station, law enforcement must agree to and be able to collect the controlled substances and other home-generated pharmaceutical waste.

Participation by any entity is voluntary and must be done in accordance with these provisions in these procedures in order to be considered a model program. Jurisdictions such as the City of Los Angeles, San Mateo County, Ventura County, Santa Cruz County, Marin County, Santa Clara County, and nonprofit groups such as the Teleosis Institute are current examples of entities implementing permanent and ongoing programs utilizing these types of venues.

A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB by the governmental entity, organization, or business that is implementing these programs. The list of collection facilities shall include the name, address, contact, and telephone number of the facility collecting and disposing of the home-generated pharmaceutical waste.

2. **Government Agency Authorization** – Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.

3. **Medical/Hazardous Waste Hauler/Disposal Arrangements** – Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at http:www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. **What Can and Cannot Be Collected**
   a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.

   b. Sharps in ~~approved~~ containers approved by the local enforcement agency may be accepted at collection sites, but shall not be placed in the same containers as the home-generated pharmaceutical waste.

   c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). ~~If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.~~

5. **Signage** – Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.), as well as the hours during which collection is permitted. Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. *Wastes commingled in this manner must be handled as medical or hazardous waste.* ~~*However, i*~~ If home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. ~~Home-generated pharmaceutical wastes shall be segregated for storage and when placed in a container or secondary container, that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction.~~ A stand alone sign may be provided by the consolidation point (facility) which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to the container location. During periods of non-operation this sign ~~shall~~may be removed and the container shall be stored in a secure ~~intermediate~~ storage area to prevent theft.

Signage should ~~also show~~include instructions on how to deposit pharmaceuticals into the secured container~~, since staff cannot assist the consumers. The~~. Any signage should also advise consumers to remove personal information from the medicine containers~~. In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer~~ but leave information as to ~~participate in a take back program.~~the type of medication being deposited.

6. **How Home-Generated Pharmaceuticals Shall Be Collected** – Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. ~~If home-generated pharmaceuticals are kept in the original, labeled container, ensure that personal information shall be~~is ~~removed or marked out, but information pertaining to the type of pharmaceutical is retained.~~ The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies ~~are not to~~ may assist consumers in placing home-generated pharmaceuticals in the bins~~. This is the obligation of the consumer.~~ if deemed necessary. The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler as specified in these procedures.

a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances – ~~If Home~~ home-generated ~~pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they shall~~ should ~~be emptied from their containers by the consumer into the secured bin/container.~~ Collection site

staff may assist a consumer in opening a container but ~~shall~~ should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

b. Storage – In accordance with Board of Pharmacy specifications~~requirements~~, ~~A~~ collection sites located in ~~at~~ pharmacies shall not commingle ~~not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated~~ pharmaceutical waste ~~shall not be placed or commingled~~ with expired, recalled or other quarantined drugs ~~in the possession of a collection site~~. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in ~~approved~~ containers~~,~~ approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in ~~approved~~ a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in ~~an~~a container approved ~~sharps disposal container. Never have employees~~by the local enforcement agency. Employees should never touch the sharps or assist in this process.

d. Chain of Custody- When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the ~~owner~~ generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that ~~it is~~ storage~~d~~, removal and transportation of full containers ~~transported,~~ and disposal~~ed~~ are ~~of~~ in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and ~~hauler~~ registration number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. **Staffing -** The following staff are recommended at collection programs to implement the specified tasks:
   a. Pharmacist (at pharmacies) – The pharmacist ~~may or may not be able~~has the discretion to assist any consumer who brings in home-generated pharmaceutical waste or review each consumer's deposit into the collection bin. ~~No pharmacist or pharmacy staff shall accept home-generated pharmaceutical waste directly from consumers.~~ The consumer shall deposit the items into the secured locked container. ~~A~~If a pharmacist~~, if he or she~~ chooses~~,~~ to assist consumers with the identification of ~~drugs~~pharmaceuticals, the pharmacist should refer customers with pharmaceuticals that ~~are unidentified, shall treat those drugs~~ have been identified as controlled substances ~~and consumers shall be referred~~ to an appropriate collection location for those items. ~~Alternatively, signage could be displayed stating that the pharmacy will not accept controlled substances for collection and disposal. Additional items that shall not be accepted into the pharmaceutical collection containers include sharps, medical waste and other items identified in the definition section of these procedures.~~

   b. Law Enforcement – If a permanent home-generated pharmaceutical waste collection program decides to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances.

   c. Hazardous Waste Company Personnel (for collection at HHW facilities) - Hazardous waste personnel ~~will~~ should provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove home-generated pharmaceutical waste, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances at a licensed hazardous waste incinerator, provide a certificate of destruction, and provide weight of materials collected. Do not allow home-generated pharmaceutical wastes that are hazardous waste (e.g. chemotherapy drugs) to be stored longer than 90 days at the facility as required for the management of hazardous waste.

   d. Medical Prescriber Staff - No physician, dentist, veterinarian or other prescriber or the staff in these offices may accept home-generated pharmaceutical waste directly from consumers. It is the consumer's responsibility to deposit the items into the secured locked container. A prescriber may assist consumers with the identification of drugs.

8. **Container Security –** It is the responsibility of the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to ~~limit~~ prevent diversion and theft opportunities and not allow staff or the entity overseeing the program from having access to the contents. Containers at permanent locations shall ~~either~~ be locked and ~~positioned so they are not moveable or~~ stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

   ~~The bins~~Bins located at pharmacies shall ~~require~~have a two ~~keys~~key security system-one in the possession of the collection site's designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner: a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.

Every collection site that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported ~~with~~ within 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. **Essential Equipment and Supplies**
   a. Pharmacies, Physicians, Veterinarians and Other Prescribers' Offices and Police Stations – The following are examples of the types of equipment and supplies that ~~shall~~ should be provided: caged, lockable secure containers, lockable kiosks, lockable steel bins, refurbished lockable mail boxes with an internal container. These types of collection containers shall be located near a building entrance or in a lobby that allows people to drop off home-generated pharmaceuticals and not be able to retrieve them, in order to prevent theft. Other supplies include black markers to ~~cover up~~ obscure personal data, signage informing the public about what can and shall not be collected.

   b. Permanent HHW Collection Facility Equipment – The following are examples of equipment and supplies ~~shall should be~~ typically used at permanent HHW collection facilities ~~provided~~: four container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gallon plastic container for mercury items), gloves, indelible markers, and sharps container and/or mail back sharps disposal kit.

10. **Budget** – In order to ensure that the program is properly run, a budget estimate should be developed so that the program is free for the public to dispose of unused and unwanted home-generated pharmaceuticals at the point of disposal. In doing so the facility will need to determine who will pay for the collection and disposal of home-generated pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected.

11. **Education and Advertising** - Collection locations operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. Educational materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceuticals. Operators shall develop and distribute materials advertising the availability of permanent collection programs. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating jurisdictions, movie theater advertisements, advertisements on buses and bus stops, print ads in recycling guides, or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

Collection location operators shall provide instructions and information for consumers ~~to use as they prepare to bring~~prior to bringing items to the collection location. These instructions should include:

a. ~~List~~ A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).

b. ~~All home-generated pharmaceutical waste must stay in their original containers; and~~ Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

~~c. Patient name and any other personal information must be rendered unreadable on the prescription label, before turning items in for collection. Blacking out with a Sharpie or other marker is suggested. Leave the name of the drug on the container.~~

12. **Data Collection** - Data shall be kept on the total number of pounds collected, the number of residents utilizing the collection facility, and when possible, the types of materials collected for further study and analysis. Examples of collection forms can be accessed at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com. Security and confidentiality measures must be taken when retaining this data.

13. **Site Visits to Collection Sites** – For programs developed and overseen by public entities, those public entities shall visit collection locations periodically to help assure that procedures are being adhered to. A collection site shall make its premises available for inspection by government agencies with jurisdiction in this area.

II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government-Sponsored One Time or Periodic Collection Events

Although permanent collection programs are the preferred method to collect and properly manage home-generated pharmaceuticals, some jurisdictions such as Tuolumne County, Fresno County, City and County of Santa Cruz, and the City of Watsonville provide One-time or Periodic Collection Events. ~~Jurisdictions offering one~~The following procedures are basic steps to implement One-time events ~~shall adhere to the following requirements~~:

1. **Collection Site -** Access to the location must be restricted to only consumers dropping off home-generated pharmaceuticals. The designated operator shall observe consumers dropping off home-generated pharmaceuticals and shall ensure that ~~none of~~ the home-generated pharmaceuticals wastes are ~~stolen.~~stored in such a manner as to prevent theft. If any theft is observed or suspected, the operator shall contact the appropriate law enforcement agency and the Local Enforcement Agency of CDPH. The collection site should include the following:

   a. Pharmacist (if a one day event is at a facility other than a pharmacy) ~~Pharmacists are~~ – It is recommended ~~to be present at the event and must be~~that a licensed ~~and~~ pharmacist in good standing with the California State Board of Pharmacy be present at the event.
   b. Dedicated Collection Area - If the collection site is at an HHW facility and the home-generated pharmaceutical waste is being segregated, the facility must provide room to account for ~~additional hazardous waste~~ secured storage of pharmaceutical collection containers.
   c. Law Enforcement - Law enforcement may participate in a collection event to provide security for event personnel~~; this~~. This is optional and at the discretion of collection organizers ~~and not required for all events.~~. A law enforcement officer is only required to attend and participate in a collection event only if

controlled substances are to be accepted at the event. ~~Only~~ Per U.S. Drug Enforcement Agency (DEA) law, only a law enforcement officer may accept controlled substances from the consumer. If controlled substances will be accepted, the operator of the event shall ask the law enforcement agency that is providing the officer if the agency has any specific requirements that the event must adhere to. For example, the law enforcement agency may specify the type of packaging that the drugs must be contained in to be accepted into their evidence locker, or if the containers the collection event will provide, are adequate for the law enforcement agency purposes. For controlled substances only, law enforcement must be on site at all times ~~be~~ and be able to see the collection and movement of the home-generated pharmaceutical wastes from the public to the collection location. Law enforcement must be able to see the transfer of home-generated pharmaceutical wastes from vehicles to the collection containers. The operator ~~shall~~ should coordinate with law enforcement to determine the appropriate position for law enforcement to be stationed.

2. **Government Agency Authorization** - Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.

3. **Medical/Hazardous Waste Hauler/Disposal Arrangements** - Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at http:www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. **What Can and Cannot Be Collected**
   a. These programs provide for the collection and disposal of home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste.

   b. Sharps in ~~approved~~ containers approved by the local enforcement agency may be accepted at collection sites~~, but shall not be placed in the same containers as the home-generated pharmaceutical waste.~~.

c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

~~c~~ d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to properly collect, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drug and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). ~~If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.~~

5. **Signage** – Signage must ~~be provided regarding~~ describe what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.~~) Home-generated pharmaceutical wastes shall be segregated for storage and, when placed in a container or secondary container, that container shall be labeled with the words "INCINERATION ONLY" or other labels approved by the CDPH on the lid and on the sides, so as to be visible from any lateral direction. A stand-alone sign may be provided by the consolidation point (facility which further describes the container as a waste pharmaceutical consolidation container.~~). Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. *Wastes commingled in this manner must be handled as medical or hazardous waste.* ~~*However, i*~~ If home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. This sign shall be located in close proximity to the container to direct consumers to container location. During periods of non-operation this sign ~~shall~~ may be removed and the container shall be stored in a secure intermediate storage area.

Signage should ~~also show~~include instructions on how to deposit pharmaceuticals into the secured container~~, since staff cannot assist the consumers. The~~. Any signage should also advise consumers to remove personal information from the medicine containers. ~~In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer to participate in a take-back program.~~

6. **How Home-Generated Pharmaceuticals Shall Be Collected**
~~Advertise where the event will take place, when it will take place, the~~the date, location, time, hours of the event, and who to contact for more information for the event. Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. ~~If home-generated pharmaceuticals are kept in the original, labeled container, personal information shall be removed or marked out. but leave information as to the type of medication being deposited.~~ The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies ~~are not to~~ may assist consumers in ~~placing~~ depositing home-generated pharmaceuticals in the bins~~. This is the obligation of the consumer.~~ when needed. The collection location must ensure that the ~~home-generated pharmaceutical licensed~~medical or hazardous waste hauler or handler transports the home-generated pharmaceutical waste for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers,

nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances ~~- If Home-generated pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they may shall be emptied from their containers by the consumer into the secured bin/container.~~ Collection site staff may assist a consumer in opening a container but ~~shall~~ should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

b. Storage - ~~A collection site shall not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated pharmaceutical waste shall not be placed or commingled with expired, recalled or other quarantined drugs in the possession of a collection site.~~ Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste must be removed the same day from the location in which the one-day or periodic event was held but may be stored at ~~a~~ secure ~~onsite~~ location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in ~~approved~~ containers~~,~~ approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in a container approved ~~container~~by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.

d. Chain of Custody - When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the ~~owner~~ generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that ~~it is~~ storage~~d~~, removal and transportation of full containers ~~transported,~~ and disposal~~ed~~ are ~~of~~ in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and ~~hauler~~ registration number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. Staffing

~~The~~Event organizers are encouraged to have the following staff ~~are required~~ at collection sites to implement the specified tasks:

a. Greeter - direct people to the collection location and answer questions. Greeters can also screen incoming people and wastes for problems. If the event is large enough, radios are useful.

b. Law Enforcement Staff - to provide security, take possession of controlled substances ~~after determination by a pharmacist~~if it has been determined that a controlled substance has been brought in by a consumer, transport controlled substances to evidence storage locker, document the collection of controlled substances, and arrange for and ensure U.S. ~~Drug Enforcement Agency~~ DEA authorized witnessed destruction of controlled substances. Law enforcement staff can also provide crowd control and watch for problem people. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with the law enforcement agency providing an officer for the event, whether they have requirements for the type of packaging the drugs must be contained in to be accepted into their evidence locker, or if containers the collection event will provide are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel. This is optional at the discretion of collection organizers and not required for all events.

c. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled home-generated pharmaceutical waste, inventory controlled substances~~,~~ (if applicable), witness, and sign the inventory.

d. Hazardous Waste Personnel - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste on the same day as the event, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, provide weight of materials collected, and complete data entry.

8. **Container Security** – It is the responsibility of the entity overseeing the collection event to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to ~~limit~~ prevent diversion and theft opportunities and not allow staff or the entity overseeing the event from having access to the contents. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

Every collection event that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported with 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. ~~Essential~~ Recommended **Equipment and Supplies**
   a. Tools for counting home-generated pharmaceutical waste (pharmacist should provide this);
   b. Hazardous waste containers;
   c. Gloves (Disposable latex or non-latex);
   d. Sealable plastic bags (One-gallon and snack size, with external slide mechanism);
   e. Extension cords, grounded;
   f. Survey forms (examples can be found at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com);
   g. Indelible markers;
   h. Packing tape;
   i. Containers- Check with your contracted medical or hazardous waste hauler for appropriate containers; ~~and~~
   j. Sharps disposal container -Provide sharps containers approved by the local enforcement agency to collect sharps if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point; and.
   k. Personal protective equipment – All staff must wear gloves (latex or non-latex) at all times when handling pharmaceutical waste. This is important as the containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) must be avoided. ~~Wearing~~The use of facemasks should be considered, especially for the pharmacist who ~~is doing~~may be conducting the physical ~~determination~~ examination of the home-generated pharmaceutical waste. ~~Do not eat or drink directly in the area that the home-generated pharmaceutical wastes are being collected. Discard used gloves.~~

10. **Budget** - An estimate of the budget should be developed and the program must be free to the public to dispose of unused and unwanted home-generated pharmaceuticals.

11. **Education and Advertising** – Collection event operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. These materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceutical waste. Event operators shall develop and distribute materials advertising for the collection event. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating

cities, movie theatre advertisements, advertisements on buses and at bus stops, print ads in recycling guides or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

Collection event operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection event:

a. ~~List~~ Date, Time, Location, operating hours, and contact information for the collection event.
b. A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste~~.~~).
c. Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

12. **Data Collection** - Determine amounts of home-generated pharmaceuticals collected along with the number of donators. If time allows, determine the types and amounts of home-generated pharmaceuticals collected. This information could be used for further studies and policy recommendations. Security and confidentiality measures should be taken when retaining this data.

    Each collection event must have a log specific to that collection event. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection event (b) the address, phone number and location number where the event was located; (c) the date the collection event took place; (d) the names of at least one person from the event who witnessed the pickup by the licensed waste hauler (e) the name of the waste hauler's staff person who picked up the collected waste; (f) the weight of home-generated pharmaceutical waste removed from collection event; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals. The log should indicate the name, address and hauler number of waste hauler taking the drugs. These records shall be kept for 3 years after the life of the collection event by the host agency.

13. **Site Visits to Collection Sites** – The event organizer shall inspect the location to ensure compliance with all requirements. The CIWMB may request a report summarizing the activities of each collection location including amounts of home-generated pharmaceutical waste collected and the number of days in operation as a collection location for home-generated pharmaceuticals.

III. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs Through a Mail Back Program

In some jurisdictions mailing back used and unused home-generated pharmaceuticals may be the only or most convenient option for the proper management of these items. An example is the State of Maine, which uses pre-paid mailing envelopes available at pharmacies, doctors' offices, and post offices~~.~~ to collect home-generated pharmaceuticals that may include controlled substances. In addition, some pharmaceutical companies, such as Celgene, will take back their own home-generated pharmaceuticals via mail. Celgene allows patients to return unused drugs such as thalidomide purchased from the company, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

Locations for Mail-Back Programs shall only be allowed if the following requirements are met:

1. Each entity overseeing either a Mail-Back Location or Mail-Back Program shall ensure that the home-generated pharmaceutical waste is destroyed in accordance with applicable regulations. CIWMB may request that each Mail-Back Location or Program provide information on the amounts of home-generated pharmaceuticals received and destroyed.

2. Determine locations where home-generated pharmaceuticals can be mailed for proper management and destruction. These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. In addition, these facilities must be able to provide data on the amounts of home-generated pharmaceuticals received and destroyed.

3. Operators of mail-back programs shall obtain self-sealing pre-addressed and pre-stamped envelopes that are approved by the U.S. Postal Service for containment and transportation of home-generated pharmaceutical waste. The envelopes shall also include an instruction sheet on how to package and send the home-generated pharmaceuticals.

4. Operators of mail back programs ~~*shall*~~ *may* provide postage-paid envelopes to pharmacies, one-time collection events, hospice care providers, doctors' offices, and post offices to ~~be provided to consumers that will~~ be utilized by consumers for the mailing and destruction of unused and expired home-generated pharmaceuticals.

5. Envelopes shall be tracked to assure that all envelopes are used for their intended purposes and that all of the home-generated pharmaceuticals get to the destruction facility.

6. ~~Operator~~ Operators ~~*shall*~~ *may* advertise its mail back program at pharmacies, convalescent homes, and retirement homes in order to inform potential users of the program of its availability and requirements for participation.

7. The operator shall review data on the amounts of home-generated pharmaceuticals collected to assure that the amounts are increasing and shall make changes to the program as needed to the program to assure continued growth.

Appendix I-Definitions

1. **Controlled Substance**-any substance listed in Chapter 2 (commencing with Section 11053) of Davison 10 of the CA Health & Safety Code.

2. **Event –** Include programs and one- time events for the collection of home-generated pharmaceutical waste to assure appropriate disposal of these items.

3. **Collection Programs** – include permanent collection programs, temporary collection programs, and mail back collection programs

4. **Model Program** - CIWMB a[p[proved program through which the public may return unused or expired home-generated that meets statutory criteria.

5. **Over the Counter Drug** - a non-prescription drug a defined per CA Business & Professions Code Section 4025.1 which states "non-prescription drugs" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the laws and rules of this state and the federal government.

6. **Collection Facility** - any entity CIWMB finds appropriate to implement or evaluate a model home-generated pharmaceutical waste program. The participant must agree to participate as a model program. Entities that may qualify to participate:

   a. Governmental entities (includes police and sheriff's stations, public/environmental health agencies and HHW facilities);
   b. Pharmacies with active unrestricted licenses from the California State Board of Pharmacy;
   c. Other Physician and other licensed health care prescribers' offices; and
   d. Healthcare Collection Sites that are licensed by the Department of Consumer Affairs

7. **Pharmaceutical Waste** - In this document it is considered to be a prescription drug dispensed to a consumer or a non-prescription item, no longer wanted or need by the consumer and includes home-generated pharmaceuticals in many delivery systems, such as pills, liquids, and inhalers.

8. **Prescription Drug** - is a dangerous drug as defined per California Business and Professions Code Section 4022 which means any drug unsafe for self-use in humans or animals, without the oversight of a licensed prescriber and includes the following:

   a. any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription, "Rx only", or words of similar import.
   b. any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to CA Business & Professions Code Section 4006.

Attachment 5

Senate Bill 26

SENATE BILL No. 26

Introduced by Senator Simitian

December 1, 2008

An act to add Sections 4001.2, 4068.1, and 4146 to the Business and Professions Code, to amend Sections 117700, 117935, 117945, 117960, 118000, 118040, 118147, and 118165 of, and to add Sections 117642, 117669, 117748, 117904.5, 118031, and 118041 to, the Health and Safety Code, and to amend Section 47200 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 26, as introduced, Simitian. Home-generated pharmaceutical waste.

The existing Pharmacy Law establishes the California State Board of Pharmacy, prescribes the licensing, regulatory, and disciplinary functions of the board, and authorizes the board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Existing law, the California Integrated Waste Management Act of 1989, requires the California Integrated Waste Management Board to adopt regulations that set forth minimum standards for solid waste management and require assurance of financial ability to pay for specified injury and property damage claims resulting from the operation of a disposal facility. The act requires the board to expend moneys from

the Solid Waste Management Account in the Integrated Waste Management Fund, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, as provided.

This bill would require that local programs to help prevent the disposal of home-generated sharps waste and home-generated pharmaceutical waste at disposal sites also be included among the types of local programs that may be funded by such a grant.

Existing law, the Medical Waste Management Act, requires the State Department of Public Health to regulate the management and handling of medical waste, as defined. Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.

This bill would also exclude home-generated pharmaceutical waste, as defined, from the definition of medical waste.

Existing law regulates the methods of consolidating, storing, and transporting medical waste and home-generated sharps waste. Violation of these provisions is a crime.

This bill would regulate consolidation points for home-generated pharmaceutical waste, as defined, as well as transportation and disposal of that waste by both hazardous waste haulers and common carriers, as defined. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4001.2 is added to the Business and Professions Code, to read:

4001.2. To further the purposes of Section 4001.1, and to protect the public from hazards caused by the improper management and disposal of waste drugs and devices, the

California State Board of Pharmacy shall coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to properly manage pharmaceutical wastes and the disposal of these wastes.

SEC. 2. Section 4068.1 is added to the Business and Professions Code, to read:

4068.1. A pharmacy may accept the return of home-generated pharmaceutical waste, as defined in Section 117769 of the Health and Safety Code, from the public.

SEC. 3. Section 4146 is added to the Business and Professions Code, to read:

4146. A pharmacy may accept the return of home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code, from a person if the waste is contained in a sharps container.

SEC. 4. Section 117642 is added to the Health and Safety Code, to read:

117642. "Common carrier" means a person or company that hauls for hire goods, including, but not limited to, pharmaceutical waste or home-generated pharmaceutical waste. Home-generated pharmaceutical waste must have been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.

SEC. 5. Section 117669 is added to the Health and Safety Code, to read:

117669. "Home-generated pharmaceutical waste" means prescribed and over-the-counter drugs derived from a household.

SEC. 6. Section 117700 of the Health and Safety Code is amended to read:

117700. Medical waste does not include any of the following:

(a) Waste generated in food processing or biotechnology that does not contain an infectious agent as defined in Section 117675.

(b) Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.

(c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains fluid blood, as provided in subdivision (d) of Section 117635.

(d) Waste ~~which~~ *that* is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.

(e) Hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste, as defined in Section 117671, *and home-generated pharmaceutical waste, as defined in Section 117669.*

(f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.

SEC. 7. Section 117748 is added to the Health and Safety Code, to read:

117748. "Pharmaceutical waste" means any pharmaceutical, prescription, or over-the-counter human or veterinary drug, including, but not limited to, a drug, as defined in Section 109925, or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(g)(1)) that meets any of the following requirements:

(a) The drug may no longer be sold or dispensed because it has expired.

(b) The drug can no longer be used for its intended purpose.

(c) The drug has been discarded.

(d) The drug has been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.

SEC. 8. Section 117904.5 is added to the Health and Safety Code, to read:

117904.5. (a) In addition to the consolidation points authorized pursuant to Section 118147, the enforcement agency may approve a location as a point of consolidation for the collection of home-generated pharmaceutical waste. These locations may include, but are not limited to, pharmacies, heath care facilities, veterinarian offices, clinics, household hazardous waste programs, solid waste facilities, senior centers, or government offices.

(b) A consolidation location approved pursuant to this section shall be known as a home-generated pharmaceutical waste consolidation point.

(c) A home-generated pharmaceutical waste consolidation point is not subject to the requirements of Chapter 9 (commencing with Section 118275) of Part 14 of Division 4, to the permit

requirements of this part, or to any permit or registration fees, with regard to the activity of consolidating home-generated pharmaceutical waste pursuant to this section.

(d) A home-generated pharmaceutical waste consolidation point shall comply with all of the following requirements:

(1) It shall be approved by the enforcement agency for this purpose.

(2) The home-generated pharmaceutical waste collected and consolidated at the facility shall be collected and contained in a leak-resistant container and placed in a secure area that does not allow the waste to be accessed or salvaged by unauthorized persons.

(3) Containers ready for disposal shall not be held for more than 90 days without the written approval of the enforcement agency.

(e) An operator of a home-generated pharmaceutical waste consolidation point that is approved pursuant to this section shall not be considered a generator of that waste.

(f) The end disposal facility that treats the home-generated pharmaceutical waste shall maintain the tracking documents required by Section 118040 or 118041, as applicable, and Section 118165 with regard to the pharmaceutical waste.

(g) Nothing in this section shall exempt any person from any federal or state law governing pharmaceuticals.

SEC. 9. Section 117935 of the Health and Safety Code is amended to read:

117935. Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite.

(f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, ~~or~~ the name of the registered hazardous waste hauler

used by the generator to have untreated medical waste removed for treatment and disposal, *and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal.*

(g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable.

(h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable.

(i) A statement certifying that the information provided is complete and accurate.

SEC. 10. Section 117945 of the Health and Safety Code is amended to read:

117945. Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

(a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.

(b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, and the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030, *or the name of the common carrier hauling pharmaceutical waste pursuant to Section 118031.* The small quantity generator shall maintain these records for not less than two years.

SEC. 11. Section 117960 of the Health and Safety Code is amended to read:

117960. Any large quantity generator required to register with the enforcement agency pursuant to Section 117950 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.
(c) The type of business.
(d) The types, and the estimated average monthly quantity, of medical waste generated.
(e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility.
(f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable, *or the name of the common carrier hauling pharmaceutical waste pursuant to Section 118031.*
(g) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe, if applicable.
(h) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.
(i) An emergency action plan complying with regulations adopted by the department.
(j) A statement certifying that the information provided is complete and accurate.
SEC. 12. Section 118000 of the Health and Safety Code is amended to read:
118000. (a) Except as otherwise exempted pursuant to Section 118030 *or 118031*, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol.

(b) Except for small quantity generators transporting medical waste pursuant to Section 118030 *or small quantity generators or common carriers transporting home-generated pharmaceutical waste pursuant to Section 118031*, medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body.
(c) A person shall not transport medical waste in the same vehicle with other waste unless the medical waste is separately contained in rigid containers or kept separate by barriers from other waste, or unless all of the waste is to be handled as medical waste in accordance with this part.
(d) Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal, pursuant to this part.
(e) Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.
(f) Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.
SEC. 13. Section 118031 is added to the Health and Safety Code, to read:
118031. Pharmaceutical waste may be shipped by a common carrier if the generator or home-generated pharmaceutical waste consolidation point meets the following requirements:
(a) The facility shall maintain documentation as required in Sections 118040 and 118041.
(b) The waste products are transported to any of the following:
(1) A medical waste facility.
(2) A hazardous waste facility.
(3) A reverse distributor, with the final destination of a medical or hazardous waste facility.

SEC. 14. Section 118040 of the Health and Safety Code is amended to read:

118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, *pharmaceutical waste or home-generated pharmaceutical waste consolidated by a home-generated pharmaceutical waste consolidation point approved pursuant to Section 117904.5, or home-generated pharmaceutical waste transported pursuant to Section 118031,* a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030.

(2) The type and quantity of medical waste transported.

(3) The name, address, and telephone number of the generator.

(4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.

(5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have a tracking document in his

or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original tracking document.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

(f) Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being transported out of the state.

SEC. 15. Section 118041 is added to the Health and Safety Code, to read:

118041. (a) A person transporting pharmaceutical waste shall maintain a completed tracking document of all pharmaceutical waste removed for treatment or disposal. A copy of the tracking document shall be included with the container holding the pharmaceutical waste.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, and telephone number of the generator.

(2) Specific information indicating that pharmaceutical waste is being transported.

(3) The name, address, and telephone number of the person transporting the waste.

(4) The name, address, telephone number, and permit number of the permitted treatment facility or transfer station to which the pharmaceutical waste is being sent.

(5) The date that the pharmaceutical waste was collected or removed from the generator or home-generated pharmaceutical waste consolidation point.

(c) A person tracking pharmaceutical waste shall have a tracking document for the waste in his or her possession while transporting the waste. The tracking document shall be shown, upon demand, to any enforcement agency personnel or officer of the Department of the California Highway Patrol.

(d) A medical waste treatment facility and transfer station shall date and sign a copy of the tracking document upon receipt, periodically provide data in a format determined by the department, and shall maintain a copy of the tracking document for three years.

(e) This section does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal of the pharmaceutical waste over a period of time, if the form or log is maintained in the files of the parent organization or other health care facility that receives the waste.

(f) Pharmaceutical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state, or if the waste is crossing an international border, the home-generated pharmaceutical waste shall be treated pursuant to Section 118222 prior to being transported out of state.

SEC. 16. Section 118147 of the Health and Safety Code is amended to read:

118147. Notwithstanding any other provision of this chapter, a registered medical waste generator, which is a facility specified in subdivisions (a) and (b) of Section 117705, may accept home-generated sharps waste *and home-generated pharmaceutical waste*, to be consolidated with the facility's medical waste stream, subject to all of the following conditions:

(a) The generator of the *home-generated* sharps waste *or home-generated pharmaceutical waste*, a member of the generator's family, or a person authorized by the enforcement agency transports the sharps waste *or pharmaceutical waste* to the medical waste generator's facility.

(b) The *home-generated* sharps waste *or home-generated pharmaceutical waste* is accepted at a central location at the medical waste generator's facility.

(c) A reference to, and a description of, the actions taken pursuant to this section are included in the facility's medical waste management plan adopted pursuant to Section 117960.

SEC. 17. Section 118165 of the Health and Safety Code is amended to read:

118165. On and after April 1, 1991, all persons operating a medical waste treatment facility shall maintain individual records for a period of three years and shall report or submit to the enforcement agency upon request, all of the following information:

(a) The type of treatment facility and its capacity.

(b) All treatment facility operating records.

(c) Copies of the tracking documents for all medical waste it receives for treatment from offsite generators or from hazardous waste haulers *or common carriers, pursuant to Section 118041*.

SEC. 18. Section 47200 of the Public Resources Code is amended to read:

47200. (a) The board shall expend funds from the account, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of *home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code, home-generated pharmaceutical waste, as defined in Section 117669 of the Health and Safety Code, and* hazardous wastes at disposal sites, including, but not limited to, programs to expand or initially implement household hazardous waste programs. In making grants pursuant to this section, the board shall give priority to funding programs that provide for the following:

(1) New programs for rural areas, underserved areas, and for small cities.

(2) Expansion of existing programs to provide for the collection of additional waste types, innovative or more cost-effective collection methods, or expanded public education services.

(3) Regional household hazardous waste programs.

(b) (1) The total amount of grants made by the board pursuant to this section shall not exceed, in any one fiscal year, three million dollars ($3,000,000).

(2) Notwithstanding paragraph (1), the total amount of grants made by the board pursuant to this section may exceed three million dollars ($3,000,000) but shall not exceed six million dollars ($6,000,000), in any one fiscal year, if sufficient funds are appropriated from the Integrated Waste Management Account for this purpose.

SEC. 19. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment 6

Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration

Docket No. DEA-316A

the proposal, that "the Commission believes DCMs benefit from endeavoring to recruit their public directors from a broad and culturally diverse pool of qualified candidates." The purpose of the acceptable practices is to "ensure that there is adequate independence within [exchange] board[s] to insulate [their] regulatory functions from the interests of the exchange's management, members and other business interests of the market itself." 71 FR 38740 (July 7, 2006). It is not clear to me how recruiting directors from a culturally diverse pool of candidates advances that goal, nor is it a given that seating a well-qualified board that is culturally diverse is something that may be practicably accomplished. My primary objection, however, is based on the fact that we have no legal authority to issue pronouncements on the subject. We are not a commission of general jurisdiction. Our authority and oversight responsibilities are specifically limited by statute and do not include the promotion of equal employment opportunity. Moreover, to the extent the Commission may be suggesting that exchanges consider factors such as race, gender, national origin, or religion in selecting public directors, we may be encouraging activity that could potentially violate Title VII of the Civil Rights Act of 1964.

Concurring Statement of Commissioner Bart Chilton Regarding the Withdrawal of Previously Proposed Amendments to the Acceptable Practices for Core Principle 15 and Solicitation of Public Comments on New Proposed Amendments

I concur in the Commission's issuance of the above-referenced action. I write separately, however, to comment on certain aspects of the proposal of particular interest to me.

First, I am gratified to see language in the proposal relating to my longstanding request that we note to designated contract markets the benefits of diversity in recruiting public directors. While this is, as stated, not a requirement under the acceptable practices, it is quite obviously a laudable and attainable goal, and one that should be encouraged.

Second, I would ask commenters to respond specifically as to whether the Commission has included within the proposal all appropriate decision-making bodies at designated contract markets, or whether the class should be broadened to include entities other than boards of directors, executive committees or similarly empowered bodies, regulatory oversight committees, and disciplinary panels.

Lastly, I note with some concern the timeline of this proposal. In November 2007, the Commission stayed the "final" acceptable practices that had been issued in February 2007. This was a necessary action, although unfortunate in that it created further delay in an already protracted and flawed process. Even more unfortunate, swift action was promised on this proposal in December 2007, yet it has taken more than a full year to see any progress. As public servants, we can and should do better to serve American consumers and businesses.

[FR Doc. E9–891 Filed 1–16–09; 8:45 am]
BILLING CODE 6351–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305, and 1307

[Docket No. DEA–316A]

RIN 1117–AB18

Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In response to concerns raised by individuals, public and private organizations, the healthcare industry, and the law enforcement community, the Drug Enforcement Administration (DEA) is soliciting information on the disposal of controlled substances dispensed to individual patients, also defined as ultimate users, as well as long term care facilities. DEA is seeking options for the safe and responsible disposal of dispensed controlled substances in a manner consistent with the Controlled Substances Act and its implementing regulations.

DATES: Written comments must be postmarked on or before March 23, 2009, and electronic comments must be sent on or before midnight Eastern time March 23, 2009.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–316" on all written and electronic correspondence. Written comments being sent via regular or express mail should be sent to the Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern time on the day the comment period closes. Commenters in time zones other than Eastern time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the

public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION** paragraph.

Legal Authority

The Drug Enforcement Administration (DEA) enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801–971) as amended. DEA regulations implementing these statutes are published in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1399. These regulations are designed to establish a framework for the legal distribution of controlled substances to deter their diversion to illegal purposes and to ensure that there is a sufficient supply of these drugs for legitimate medical, scientific, research, industrial, and other purposes. Controlled substances are those substances listed in the schedules of the CSA and 21 CFR 1308.11–1308.15, and generally include narcotics, stimulants, depressants, and hallucinogens that have a potential for abuse and physical and psychological dependence, as well as anabolic steroids.

The CSA and DEA's regulations require that persons involved in the manufacture, distribution, research, dispensing, import, and export of controlled substances register with DEA (unless exempt), keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.

Background

Under the CSA, Congress established a "closed system" of distribution designed to prevent the diversion of controlled substances.[1] As part of this closed system, all persons who lawfully handle controlled substances must be registered with DEA or exempt from registration by the CSA or DEA regulations. Another central element of this closed system is that DEA registrants must maintain strict records of all transactions in controlled substances. Consistent with the CSA requirements, current DEA regulations employ a system to account for all controlled substances received, stored, distributed, dispensed, or otherwise disposed of. Under this system, all controlled substances used in legitimate commerce may be transferred only between persons or entities who are DEA registrants or who are exempted from the requirement of registration, until they are dispensed to the ultimate user. Thus, for example, a controlled substance, after being manufactured by a DEA-registered manufacturer, may be transferred to a DEA-registered distributor for subsequent distribution to a DEA-registered retail pharmacy. After a DEA-registered practitioner, such as a physician or a dentist, issues a prescription for a controlled substance to a patient (i.e., the ultimate user), that patient can fill that prescription at a retail pharmacy to obtain that controlled substance. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are all required to be DEA registrants, or to be exempted from the requirement of registration, to participate in the process.

As set forth in the CSA, an ultimate user is exempt from the requirement of registration—but only to the extent the ultimate user possesses a controlled substance that has been lawfully obtained for his own use or the use of a member of his household or for an animal owned by him or by a member of his household (21 U.S.C. 822(c)(3), 802(27)). Beyond such circumstances, the CSA and its implementing regulations do not currently contemplate a situation in which an ultimate user would distribute a controlled substance. Thus, such distribution, regardless of the purpose, is illegal.

Under the Controlled Substances Act, specifically 21 U.S.C. 802(27), the term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household. Ultimate users are not required to register with DEA to possess controlled substances.

Every person who manufactures or distributes any controlled substance or List I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or List I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him (21 U.S.C. 822(a)). "The term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical" (21 U.S.C. 802(11)). "The terms 'deliver' or 'delivery' mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship." (21 U.S.C. 802(8)). Thus, because the terms deliver and distribute, as defined in the CSA, encompass all methods of delivery and distribution of controlled substances, and because the CSA allows ultimate users to obtain and possess controlled substances solely for purposes of use, under current law, an ultimate user may not deliver or distribute controlled substances for purposes of disposal (unless the ultimate user is also a DEA registrant).

DEA issues registrations to certain business firms, called reverse distributors, to authorize them to take controlled substances that are expired or otherwise unwanted from other DEA registrants for subsequent disposal or distribution back to the manufacturer. Reverse distributors are the only DEA registrants permitted to receive controlled substances from other registrants expressly for the purpose of disposal; other registrants, e.g., pharmacies, may dispose of controlled substances already in their possession that have expired, been damaged, or contaminated, but may not accept controlled substances from another person solely for the purpose of disposal. Under 21 CFR 1300.01(b)(41):

> The term "reverse distributor" means a registrant who receives controlled substances acquired from another DEA registrant for the purpose of—
>
> (i) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or
>
> (ii) Where necessary, processing such substances or arranging for processing such substances for disposal.

DEA issues these firms registrations as reverse distributors and they must adhere to certain security and recordkeeping requirements to ensure that unwanted controlled substances are accounted for and disposed of in accordance with all relevant State and

[1] H.R. Rep. No. 91–1444 at 3 (1970).

Federal laws and regulations. In addition, reverse distributors must adhere to any local, county, State, and/or Federal environmental regulations when they dispose of the unwanted controlled substances. While a reverse distributor is registered by DEA at a specific location and is permitted to store controlled substances at that location, it is important to note that the reverse distributor is not required to dispose of the controlled substances at its registered location. Opportunities for large scale disposal (including by reverse distributors) of unused or expired controlled substances have been complicated by existing statutory requirements under the Controlled Substances Act and Federal and State waste disposal laws.

By regulation, a reverse distributor cannot take unwanted controlled substances from non-DEA registrants. For example, as stated previously, once a controlled substance has been dispensed to a patient as the ultimate user, either by prescription or through other means, the ultimate user cannot give the controlled substance to a reverse distributor. Such furnishing of a controlled substance by the ultimate user would be a distribution, which an ultimate user is not permitted to make without being registered. Further, the reverse distributor cannot currently take custody of the controlled substance because reverse distributors are only permitted to receive controlled substances from other DEA registrants. Members of the public have told DEA that the inability to use a reverse distributor in the disposal process is one of the reasons that ultimate users have difficulty safely disposing of unwanted medications, especially controlled substances.

Aside from ultimate users not being permitted to distribute controlled substances for purposes of disposal without being separately registered and reverse distributors not being permitted to receive controlled substances from non-registered ultimate users, recordkeeping requirements also apply to the disposal of controlled substances. The CSA requires every registrant who manufactures, distributes, or dispenses a controlled substance or substances to maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant (21 U.S.C. 827(a)(3)). Records must contain such information as the Attorney General requires to be kept by regulation (21 U.S.C. 827(b)(1)). For reverse distributors, these records include, for each controlled substance in finished form, the following:

(i) The name of the substance.

(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).

(iii) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received.

(iv) The number of commercial containers of each such finished form distributed back to the original manufacturer of the substance or manufacturer's agent, including the date of and number of containers in each such distribution and the name, address, and registration number of the manufacturer or manufacturer's agent to whom the containers were distributed.

(v) The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

(21 CFR 1304.22(e)(2))

Based on current law and DEA regulations, if ultimate users were otherwise permitted to provide their unwanted controlled substances to reverse distributors then the above recordkeeping requirements would continue to apply to the reverse distributors, unless an exemption is granted by regulation pursuant to 21 U.S.C. 827(c)(3).

Redistribution or Reuse

As discussed below, nonregistrants may dispose of controlled substances upon instruction by DEA Special Agents in Charge. However, no provisions in the CSA or DEA regulations allow a DEA registrant to routinely acquire controlled substances from a non-registrant (i.e. individual patient). Hence, patients are currently prohibited from furnishing controlled substances to reverse distributors for disposal and from returning controlled substances to a registrant for the purpose of redistribution or reuse. According to the National Conference of State Legislatures, in 2007, 10 States passed laws allowing or encouraging the donation of unused pharmaceutical drugs. Many of these programs involve health care facilities, nursing homes or other pharmacies. However, the CSA and current DEA regulations prohibit ultimate users from delivering or distributing controlled substances—even if such distribution takes the form of a donation to a DEA registrant participating in one of these State authorized programs—and prohibit registrants from accepting such donations from ultimate users. Consequently, these State laws do not provide a mechanism consistent with Federal law for donation, return, or reuse of controlled substances.

The Food and Drug Administration (FDA) does not generally permit the redistribution of medications, except under limited circumstances. The FDA Compliance Policy Guides Manual, Chapter 4, Human Drugs, Section 460.300 reads as follows:

Sec. 460.300 Return of Unused Prescription Drugs to Pharmacy Stock (CPG 7132.09)

POLICY:

A pharmacist should not return drugs [sic] products to his stock once they have been out of his possession. It could be a dangerous practice for pharmacists to accept and return to stock the unused portions of prescriptions that are returned by patrons, because he would no longer have any assurance of the strength, quality, purity or identity of the articles.

Many state boards of pharmacy have issued regulations specifically forbidding the practice. We endorse the actions of these State boards as being in the interest of public health.

The pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise, should he mix returned portions of drugs to his shelf stocks. Some of our investigations in the past have shown that drugs returned by patrons and subsequently resold by the pharmacist were responsible for injuries.[2]

DEA shares similar concerns regarding the redistribution of controlled substances. This practice is not addressed by the CSA or its implementing regulations.

Disposal of Unused or Unwanted Medications by Ultimate Users

As stated previously, the CSA and its implementing regulations do not contemplate a situation in which an ultimate user would distribute controlled substances. However, 21 CFR 1307.21 provides the procedure for disposing of controlled substances by persons who are not registrants. This procedure involves the nonregistrant submitting a letter to the local DEA Special Agent in Charge. The letter must include the name and address of the person; the name and quantity of each controlled substance to be disposed of; how the applicant obtained the controlled substance, if known; and the name, address, and registration number, if known, of the person who possessed

[2] Food and Drug Administration, *Compliance Guides Policy Manual* Section 460.300, Return of Unused Prescription Drugs to Pharmacy Stock (CPG 7132.09). October 1, 1980. *http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-300.html.*

the controlled substances prior to the applicant, if known (21 CFR 1307.21(a)(2)). Provided such disposal is permissible under the CSA, the Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance through any of the following methods: Transfer of the substance to a person registered under the CSA and authorized to possess the substance; delivery to an agent of the Administration or to the nearest office of the Administration; by destruction in the presence of an agent of the Administration or other authorized person; or, by such other means as the Special Agent in Charge may determine to ensure that the substance does not become available to unauthorized persons (21 CFR 1307.21(b)). Though this is an option currently available to ultimate users, it is used in extremely limited circumstances.

Another option available for the disposal of unwanted controlled substances dispensed to ultimate users is through take-back programs that comply with applicable Federal and state law. Take-back programs are organized collection events designed to reduce the amount of unwanted or unused pharmaceuticals that may pose a risk to public health and safety, may be accessible to diversion, or that otherwise may be disposed of in a manner that does not comply with State or Federal laws or regulations. As previously stated, the distribution of a controlled substance by an ultimate user for the purpose of disposal is a scenario not contemplated by the CSA and its closed system of distribution. However, as indicated above, ultimate users, and other DEA nonregistrants, in possession of controlled substances may dispose of those substances by receiving permission from the local DEA Special Agent in Charge, provided such disposal takes place in a manner consistent with the structure of the CSA.

In the absence of regulations expressly addressing the disposal of controlled substances dispensed to ultimate users, DEA has recently granted temporary permission to law enforcement agencies who have requested authorization to accept for disposal controlled substances that have been dispensed to ultimate users. In granting such temporary authorization, DEA has imposed certain conditions to ensure that the controlled substances do not become available to unauthorized persons, consistent with 21 CFR 1307.21, and to promote consistency with the structure of the CSA. Thus, the only take-back programs for which DEA has recently granted temporary allowances are those in which law enforcement officials directly receive the controlled substances from the ultimate users. Recognizing that there might be additional appropriate methods of allowing for the disposal of controlled substances dispensed to ultimate users, DEA is seeking information to provide more accessible ways to safely and responsibly dispose of dispensed controlled substances in a manner consistent with the CSA.

Disposal of Unused Medications by Long Term Care Facilities (LTCFs)

The term "long term care facility" (LTCF) is defined to mean "a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients." (21 CFR 1300.01(b)(25)). Most LTCFs are not DEA registered entities.

When patients residing at LTCFs require controlled substances their practitioner issues a prescription which is usually dispensed for the full amount by a registered pharmacy. The LTCF holds the prescribed drugs in a custodial manner for the patient and dispenses the medications on the schedule the practitioner orders. As a result of these dispensing practices, when patients die, leave the facility, or their medication is discontinued or changed, the LTCF may be left with excess controlled substances that must be disposed of to avoid diversion.

DEA has been acutely aware of the problems surrounding the disposal of dispensed controlled substances at LTCFs for some time, and has worked to reduce the accumulation of controlled substances at LTCFs through a number of regulatory actions. Prescribing practitioners are required by regulation to specify the quantity prescribed on the prescriptions. However, DEA recognized that LTCF patients are a unique part of society, and may often need the Schedule II controlled substances medications they are prescribed changed on short notice based on their rapidly changing health conditions. Consequently, patients might not need the full quantity of the Schedule II controlled substance that the practitioner had initially prescribed. To reduce the potential excess amounts of dispensed controlled substances, practitioners prescribing Schedule II controlled substances for LTCF patients needed the ability to prescribe smaller quantities of those substances more frequently than would be necessary for other patients. Practitioners are required to manually sign prescriptions for Schedule II controlled substances for the prescription to be valid (21 CFR 1306.05(a)), and the dispensing pharmacy is unable to dispense the needed controlled substance until it receives a valid prescription (21 CFR 1306.11(a)). It became evident that this requirement made it more difficult for prescribing practitioners to be responsive to the immediate and changing needs of LTCF patients. To address this circumstance, DEA promulgated regulations that permit the facsimile transmission of written, manually signed Schedule II prescriptions for residents of LTCFs by the practitioner or the practitioner's agent to the dispensing pharmacy (21 CFR 1306.11(f)). The facsimile serves as the original prescription for the dispensing pharmacy's records. DEA has also permitted the facsimile transmission of written, manually signed Schedule II controlled substance prescriptions for patients enrolled in hospice care programs certified and/or paid for by Medicare under Title XVIII of the United States Code, or hospice programs licensed by the State (21 CFR 1306.11(g)).

DEA has also established partial dispensing provisions for Schedules II–V prescriptions (including unit-dose dispensing, if desired), to limit the quantity of controlled substances dispensed at one time and avoid waste if the treatment was changed or discontinued. These regulations include specific provisions for residents of LTCFs or patients with medical diagnoses documenting a terminal illness (21 CFR 1306.13(b), 1306.23). According to the pharmacy industry, however, dispensing fees, reimbursement practices, and difficulties in educating practitioners regarding the need to prescribe controlled substances in anticipation of a patient's actual need for the controlled substance have, for the most part, precluded using that approach.

To further prevent the accumulation of controlled substances at LTCFs, DEA has permitted retail pharmacies to install and operate automated dispensing systems (ADS) at LTCFs (21 CFR 1301.27). ADS are conceptually similar to a vending machine. A pharmacy stores bulk controlled substances in the ADS in separate bins or containers and programs and controls the ADS remotely. Only authorized staff at the LTCF has access to the ADS's contents, which are dispensed on a single-dose basis at the time of administration pursuant to a prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the controlled substances are not considered dispensed until the system provides them,

controlled substances in the ADS are pharmacy stock, not waste.

Despite DEA's efforts to reduce the accumulation of dispensed controlled substances at LTCFs, accumulation continues to be a concern. LTCFs that are not DEA registrants may not transfer the controlled substances to either the pharmacy that supplied them or to a reverse distributor for disposal.

Purpose of Advance Notice of Proposed Rulemaking

On February 20, 2007, in recognition of the advice being provided by environmental organizations to the public to dispose of medications in household trash (as opposed to flushing them into the waste-water system), the U.S. Office of National Drug Control Policy (ONDCP) announced guidelines for the disposal of ultimate user medications, including dispensed controlled substances. The guidelines were published by ONDCP in conjunction with the Department of Health and Human Services (HHS), and the EPA.[3] The guidelines advise the public to flush medications only if the prescription label or accompanying patient information specifically states to do so. Instead of flushing, ONDCP recommends that, after performing a minimal deactivation procedure, the medications be disposed of in common household trash or at community pharmaceutical "take-back" programs. The press release announcing the guidelines stated:

> The new Federal guidelines are a balance between public health concerns and potential environmental concerns. "While EPA continues to research the effects of pharmaceuticals in water sources, one thing is clear: Improper drug disposal is a prescription for environmental and societal concern," said EPA Administrator Stephen L. Johnson. "Following these new guidelines will protect our Nation's waterways and keep pharmaceuticals out of the hands of potential abusers."

In addition to environmental concerns, there are safety concerns that medications, especially controlled substances, could be either intentionally or unintentionally abused. Children may retrieve a medication from the trash and ingest it without the specific intention of abusing it. For these reasons, some medications include flushing disposal instructions to make them less available and to mitigate safety risks.

[3] Office of National Drug Control Policy, Executive Office of the President. Proper Disposal of Prescription Drugs. February 2007. *http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf.*

The illicit use of prescription medication is a growing problem among young adults. According to the 2007 National Survey on Drug Use and Health, more persons age 12 and above are engaged in the non-medical use of psychotherapeutic drugs than those abusing cocaine, heroin, and methamphetamine combined. Prescription drug abuse is second only to marijuana use.[4] The 2005 Partnership Attitude Tracking Study (PATS) reported that 62 percent of teens say prescription pain relievers are easy to get from parents' medicine cabinets.[5]

DEA is seeking options for the disposal of controlled substances dispensed to DEA nonregistrants that protect public health and safety, minimize the possibility of diversion, are consistent with the CSA and DEA regulations, and provide sound environmental solutions.

Request for Information

DEA seeks comments regarding the promulgation of regulations to permit the disposal of controlled substances by ultimate users and long term care facilities consistent with the Controlled Substances Act and its implementing regulations. DEA seeks comments regarding how various entities would address the issue of the disposal of dispensed controlled substances held by DEA nonregistrants in light of the current restrictions that are in place. Commenters are encouraged to include the question number enumerated below in their response. Although all comments are welcome, DEA is particularly interested in comments regarding the questions listed below. These questions are separated into groups by area of interest. The groups are:

- Ultimate Users
- State and Local Law Enforcement Agencies & Publicly Owned Treatment Works
- Concerned Interest Groups
- Long Term Care Facilities
- Hospices and In-Home Care Groups
- Pharmacies
- Narcotic Treatment Programs
- Reverse Distributors
- State Regulatory Agencies
- All Interested Parties

[4] Office of National Drug Control Policy, Executive Office of the President. Prescription for Danger, A Report on the Troubling Trend of Prescription and Over-the-Counter Drug Abuse Among the Nation's Teens. January 2008.

[5] Partnership for a Drug-Free America, The Partnership Attitude Tracking Study (PATS): Teens in grades 7 through 12 (2005). May 16, 2006.

For Ultimate Users (Patients or Family Members of Patients Who Possess Controlled Substances Which Have Been Legally Dispensed)

1. Can you distinguish a controlled substance from a non-controlled substance?
2. Why do you have unwanted or outdated controlled substances in your possession?
3. What method, if any, do you currently use to dispose of your unwanted or outdated pharmaceuticals, including controlled substances?
4. Are you willing to seek locations outside of your home to dispose of unwanted pharmaceuticals?
5. Does your community, county, or State have laws, regulations, or policies in place that prohibit medications, including controlled substances, from being flushed or placed in the garbage?
6. Does your community have take-back programs during which you can provide pharmaceuticals to an entity for disposal? If so, do you know whether these programs accept controlled substances?
7. If your community has take-back programs, who sponsors the program?
8. If you participated in a take-back program, please describe how the program worked.
9. If you participated in a take-back program, was a law enforcement agency involved?
10. If you participated in a take-back program, did you encounter any problems? Please explain.
11. What do you believe is the best method of disposing of unwanted or outdated pharmaceuticals, including controlled substances dispensed to ultimate users?
12. Would you be willing to pay a fee to have your medication disposed of in a manner that minimizes the possibility of the diversion of legally obtained controlled substance medications for illegal purposes and is environmentally safe? If so, how much would you be willing to pay?
13. Would you consider using a postage paid mailing container to dispose of unwanted medications?
14. Where would you be willing to go to obtain such a postage paid mailing container (e.g., local pharmacy, police department, take-back event)?
15. Would you be willing to pay the postage on a mailing container used to ship controlled substances and other pharmaceuticals to another location for disposal? If so, how much would you be willing to pay?
16. Would you consider the use of a mailing container more convenient or less convenient than taking unwanted

controlled substances to a pharmacy or to a take-back event?

17. What other means of disposal would you consider convenient?

For State and Local Law Enforcement Agencies and Publicly Owned Treatment Works

18. Is the disposal of unwanted or outdated pharmaceuticals a problem in your area?

19. Do individuals bring their unwanted or outdated pharmaceuticals, including controlled substances which have been legally obtained, to your department for disposal?

20. Does your department encourage or discourage such activity? Please explain.

21. If individuals bring their unwanted or outdated pharmaceuticals, including controlled substances which have been legally obtained, to your department for your department to dispose of, how does that process work? Do individuals drop the pharmaceuticals in a container, hand them to a department employee, or hand them to a law enforcement officer?

22. Have you ever had any challenges or difficulties with taking individuals' unwanted or outdated pharmaceuticals, including controlled substances, for disposal? If so, please explain.

23. Does your department/facility participate in take-back programs?

24. If your department/facility participates in take-back programs, what is the nature of your participation?

25. Have you ever encountered any challenges or difficulties when participating in such programs? Please explain.

26. If your department/facility does not participate in take-back programs, what, if anything, prevents such participation?

27. Does your department/facility have the staffing and resources to participate in take-back programs?

28. Is your department aware of any cases of diversion involving take-back programs? If so, did the diversion result in the arrest or prosecution of any individuals?

29. Regardless of how you receive the medications (e.g., take-back program, individual drop off) for disposal, do you differentiate between controlled substances and noncontrolled substances? If so, how?

30. Regardless of how you receive the medications for disposal, what would you estimate to be the percentage, quantity, or other measurable unit of controlled substances as compared to noncontrolled substances?

31. Regardless of how you receive the medications for disposal, prior to disposal, where do you store these pharmaceuticals and under what security?

32. How do you dispose of the controlled substances that you receive?

33. What records do you generate regarding what you receive and what you dispose of?

34. How far must you travel to dispose of pharmaceuticals, including controlled substances?

35. What do you do if the landfill or incinerator you plan to use is closed, nonoperational, or otherwise unavailable?

36. How much money has your participation in pharmaceutical disposal cost your department/facility in the previous year?

37. How many man-hours has your participation in drug disposal cost your department/facility in the previous year?

38. If you are receiving unwanted or outdated pharmaceuticals for disposal, are you doing so as a result of local or State policy, law, or regulation?

39. If your department does not currently receive pharmaceuticals for disposal, would it be interested in receiving them?

40. Would your department/facility be willing to make available postage paid envelopes to be used by the public to mail pharmaceuticals to a reverse distributor or a law enforcement agency for disposal?

41. What do you believe is the best method of safely disposing of unwanted or outdated controlled substances held by DEA nonregistrants?

For Concerned Interest Groups

42. What prompted you to get involved in the issue of drug disposal?

43. What is your group doing to address this issue?

44. What have been your successes?

45. What challenges or difficulties have you encountered?

46. If you accept medications for disposal, what records do you maintain, if any?

47. If you accept medications for disposal, how do you store and secure these medications prior to disposal?

48. If you accept medications for disposal, do you differentiate between controlled substances and noncontrolled substances? If so, how?

49. What has been law enforcement's involvement in the disposal of these medications, if any?

50. What would you estimate to be the percentage, quantity, or other measurable unit of controlled substances as compared to noncontrolled substances that your disposal programs received?

51. If you have a pharmaceutical disposal program in place, how is it funded?

52. There is concern that residue from pharmaceuticals is being found in drinking water. What is your understanding of the percentage of this problem that is due to ultimate users flushing their unused or unwanted medications?

For Long Term Care Facilities

53. Is the issue of unwanted or unused pharmaceuticals, including controlled substances, a concern at your facility?

54. What are the reasons why your facility is in possession of unwanted or outdated pharmaceuticals, including controlled substances?

55. At the end of each month is your facility in possession of a significant amount of unwanted or outdated pharmaceuticals? How much? Of those pharmaceuticals, what would you estimate the percentage of controlled substances to be?

56. How do you normally dispose of these pharmaceuticals, including controlled substances?

57. Does law enforcement, or some other State agency, assist you in disposing of controlled substances?

58. Are you mandated by any local or State law or regulation to dispose of these medications, including controlled substances, in a specific manner? If so, how?

59. Does your facility take unwanted or outdated pharmaceuticals to local take-back programs?

60. Are you aware of automated dispensing systems? If so, does your facility use them? Have they reduced the amount of excess medications at the facility?

61. Has the ability of a pharmacy to receive faxed schedule II prescriptions for patients in long term care facilities helped to reduce the amount of excess medications at your facility?

62. How do you believe the accumulation of unwanted or outdated pharmaceuticals at long term care facilities can be better addressed?

63. What do you believe is the best method for disposing of these pharmaceuticals?

For Hospices and In-Home Care Groups

64. Is the accumulation of unwanted or outdated controlled substances a problem for your business?

65. If you dispose of unwanted or outdated pharmaceuticals, what methods do you currently use to dispose of such pharmaceuticals, including controlled substances?

66. If you dispose of pharmaceuticals, including controlled substances, what have been your successes?

67. If you dispose of pharmaceuticals, including controlled substances, what challenges or difficulties have you encountered?

68. What do you believe is the best method of disposing of these unwanted or outdated pharmaceuticals, including controlled substances?

69. Has the ability of a pharmacy to receive faxed schedule II prescriptions for patients enrolled in hospice programs helped to reduce the amount of excess medications?

70. How do you believe the accumulation of unwanted or outdated pharmaceuticals by patients enrolled in hospice programs can be better addressed?

For Pharmacies

71. Is the disposal of unwanted or outdated pharmaceuticals by ultimate users a problem in your area?

72. Does your State permit your pharmacy to take unwanted or outdated pharmaceuticals, including dispensed controlled substances, from ultimate users?

73. Does your State permit your pharmacy to place unwanted or outdated pharmaceuticals obtained from ultimate users, including dispensed controlled substances, back into stock?

74. If you provide pharmaceuticals, including controlled substances, to long term care facilities, does your State permit your pharmacy to take back unwanted, unused, or outdated medications from those facilities?

75. Does your State permit your pharmacy to place unwanted or outdated pharmaceuticals obtained from long term care facilities, including dispensed controlled substances, back into stock?

76. Does your pharmacy participate in any pharmaceutical take-back programs? If so, please describe.

77. If your pharmacy participates in pharmaceutical take-back programs, what have been the successes?

78. If your pharmacy participates in pharmaceutical take-back programs, what challenges or difficulties have you encountered?

79. Would your pharmacy be willing to make available postage paid envelopes to be used by the public to mail unwanted or outdated pharmaceuticals to a reverse distributor or law enforcement agency for disposal? Would your pharmacy consider paying for any costs associated with this activity? If so, how much would your pharmacy be willing to pay?

80. Would your individual pharmacy or chain consider contributing financially to offset the expense of a pharmaceutical disposal program? If so, what type of program is your pharmacy interested in?

81. What do you believe is the best method to dispose of unwanted or outdated pharmaceuticals obtained from ultimate users, including dispensed controlled substances?

82. Has the ability of a pharmacy to receive faxed schedule II prescriptions for patients enrolled in hospice programs or residing at long term care facilities helped to reduce the amount of excess medications?

83. How can the accumulation of unwanted or outdated pharmaceuticals, including controlled substances, at long term care facilities and hospice programs be better addressed?

For Narcotic Treatment Programs

84. What are the concerns of narcotic treatment programs regarding the disposal of controlled substances used in maintenance or detoxification treatment?

85. Would your narcotic treatment program consider contributing financially to offset the expense of a pharmaceutical disposal program? If so, what type of program would best meet your needs?

86. What do you believe is the best method to dispose of unwanted or outdated dispensed controlled substances?

87. What are the reasons why NTPs are in possession of controlled substances that require disposal?

88. Have controlled substances awaiting disposal been a source of diversion for your NTP?

For Reverse Distributors

89. Have you been approached by any group or any law enforcement agency requesting that you participate in the disposal of pharmaceuticals, including controlled substances dispensed to ultimate users?

90. Do you currently accept pharmaceuticals, including dispensed controlled substances, from ultimate users for disposal? If so, how?

91. Are your competitors accepting pharmaceuticals, including dispensed controlled substances, from ultimate users for disposal?

92. If you accept pharmaceuticals, including dispensed controlled substances, from ultimate users for disposal, what have your successes been?

93. If you accept pharmaceuticals, including dispensed controlled substances, from ultimate users for disposal, what challenges or difficulties have you encountered?

94. If you were able to accept pharmaceuticals, including dispensed controlled substances, from ultimate users for disposal, would your facility be able to handle this added volume?

95. What does it cost to dispose of controlled substances?

96. What do you estimate it would cost to dispose of controlled substances dispensed to ultimate users? On what basis are costs calculated (e.g., per pound disposed of)?

97. Do you currently accept pharmaceuticals from long term care facilities (LTCFs) for disposal? If so, how?

98. Are your competitors accepting pharmaceuticals from LTCFs for disposal?

99. If you accept pharmaceuticals from long term care facilities for disposal, what have your successes been?

100. If you accept pharmaceuticals from long term care facilities for disposal, what challenges or difficulties have you encountered?

101. If you were able to accept pharmaceuticals, including dispensed controlled substances, from long term care facilities for disposal, would your facility be able to handle this added volume?

102. What do you estimate it would cost to dispose of dispensed controlled substances obtained from long term care facilities? On what basis are costs calculated (e.g., per pound disposed of)?

103. What do you believe is the best method of disposing of unwanted or outdated pharmaceuticals, including controlled substances dispensed to DEA nonregistrants?

104. Would you accept for disposal controlled substances that have been dispensed to ultimate users directly from ultimate users by means of individual mailing containers?

105. Do you perceive any problems with reverse distributors accepting dispensed controlled substances directly from ultimate users by means of individual mailing containers?

106. Would your company be interested in contributing financially to offset the expense of a disposal program for ultimate users that would be instituted at your company?

107. If reverse distributors were permitted to accept controlled substances dispensed to ultimate users for disposal, how do you believe the unwanted or outdated controlled substances should be provided by the ultimate user to the reverse distributor?

For State Regulatory Agencies

108. What current laws or regulations does your State have regarding the disposal of dispensed controlled substances and noncontrolled substances by ultimate users?

109. What laws or regulations, if any, is your State considering regarding the disposal of dispensed controlled or noncontrolled substances by ultimate users?

110. Does your State agency participate in any initiatives (e.g., take-back or mail-back programs) regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users at this time? If so, please describe.

111. Is your State agency aware of any cases of diversion regarding take-back programs? If so, did the diversion result in the arrest or prosecution of any individuals?

112. If your State agency does not participate in any initiatives regarding the disposal of dispensed controlled or noncontrolled substances by ultimate users, why not?

113. If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, what would you estimate to be the percentage, quantity, or other measurable unit of controlled substances as compared to noncontrolled substances received?

114. If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, does your agency fund all or part of the initiative? If other funding is received, who provides the other funding?

115. If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, what successes have you seen regarding these initiatives?

116. If your State agency participates in any initiatives regarding the disposal of dispensed controlled and noncontrolled substances by ultimate users, what challenges or difficulties have you encountered?

For All Interested Parties

117. DEA also seeks comment from all interested parties regarding the funding of the disposal of unwanted or outdated controlled substances held by DEA nonregistrants.

Regulatory Certifications

This action is an Advance Notice of Proposed Rulemaking (ANPRM). Accordingly, the requirement of Executive Order 12866 to assess the costs and benefits of this action does not apply. Rather, among the purposes DEA has in publishing this ANPRM is to seek information from the public on the costs, benefits, and other impacts pertaining to the disposal of controlled substances dispensed to ultimate users and long term care facilities. Similarly, the requirements of section 603 of the Regulatory Flexibility Act do not apply to this action since, at this stage, it is an ANPRM and not a "rule" as defined in section 601 of the Regulatory Flexibility Act. Following review of the comments received to this ANPRM, if DEA promulgates a Notice or Notices of Proposed Rulemaking regarding this issue, DEA will conduct all analyses required by the Regulatory Flexibility Act, Executive Order 12866, and any other statutes or Executive Orders relevant to those rules and in effect at the time of promulgation.

Dated: January 13, 2009.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. E9–1056 Filed 1–16–09; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 180

Office of the Secretary

49 CFR Part 80

Federal Railroad Administration

49 CFR Part 261

Federal Transit Administration

49 CFR Part 640

Maritime Administration

49 CFR Part 1700

[Docket No. DOT–OST–2009–0004]

RIN 2105–AD70

Credit Assistance for Surface Transportation Projects

AGENCIES: Federal Highway Administration (FHWA), Federal Railroad Administration (FRA), Federal Transit Administration (FTA), Maritime Administration (MARAD), Office of the Secretary of Transportation (OST), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: Recent changes to the Transportation Infrastructure Finance and Innovation Act (TIFIA) statute require changes in the TIFIA rule. In addition, the DOT has gained substantial administrative experience since the TIFIA rule was last amended in 2000. The DOT proposes to amend the TIFIA rule to implement the recent statutory changes and to incorporate certain other changes to the rule that it considers will improve the efficiency of the program and its usefulness to borrowers. In addition, the DOT seeks comment on policy issues with potentially significant impact on the TIFIA project selection process.

DATES: Comments must be received on or before March 23, 2009.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or submit comments electronically at *http://www.regulations.gov,* or fax comments to (202) 493–2251. Alternatively, comments may be submitted via the Federal eRulemaking Portal at *http://www.regulations.gov* (follow the on-line instructions for submitting comments). All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. All comments received into any docket may be searched in electronic format by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Persons making comments may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Pages 19477–78), or you may view the statement at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Mark Sullivan, TIFIA Joint Program Office (202) 366–5785, or Mr. Steven Rochlis, Office of the Chief Counsel (202) 366–1395, Federal Highway Administration; Mr. Michael Bouril, Office of Budget (202) 366–4587, Mr. Jacob Falk, Office of Policy (202) 366–

Attachment 7

Assembly Bill 718 Prescription Drugs/Electronic Transmission

ASSEMBLY BILL No. 718

Introduced by Assembly Member Emmerson

February 26, 2009

An act to add Section 4071.2 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 718, as introduced, Emmerson. Prescription drugs: electronic transmissions.

The Pharmacy Law regulates, among other matters, the dispensing by prescription of dangerous devices and dangerous drugs, which include controlled substances. Existing law authorizes the electronic transmission of prescriptions under specified circumstances. Under existing law, a violation of the Pharmacy Law is a crime.

This bill would require every licensed prescriber, or prescriber's authorized agent, or pharmacy operating in California to have the ability, on or before January 1, 2012, to transmit and receive prescriptions by electronic data transmission. Because a knowing violation of that provision would constitute a crime under the Pharmacy Law, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4071.2 is added to the Business and Professions Code, to read:

4071.2. On or before January 1, 2012, every licensed prescriber, prescriber's authorized agent, or pharmacy operating in California shall have the ability to transmit and receive prescriptions by electronic data transmission.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.

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Attachment 8

New CURES Vendor

EDMUND G. BROWN JR.
Attorney General

State of California
DEPARTMENT OF JUSTICE

BUREAU OF NARCOTIC ENFORCEMENT
P.O. BOX 161089
SACRAMENTO, CA.95816-1089
Telephone: 319-9062
Fax: 319-9448

December 9, 2008

Re: **New Data Collection Vendor for California's Prescription Monitoring Program**

Dear Pharmacist:

As you may be aware, the Department of Justice uses a third party vendor to collect controlled substance prescription data as defined under Health & Safety Code Section 11165, Controlled Substance Utilization Review and Evaluation System (CURES). That vendor has been Atlantic Associates Inc. for the last 10 years; however, due to the state of California's competitive bid process a new vendor has been awarded this contract effective January 1, 2009. Therefore, the submission process for submitting controlled substance prescription data will change.

Effective January 1, 2009, all controlled substance prescription data must be submitted to Infinite Solutions, Inc on a weekly basis. Infinite Solutions will continue to support the ASAP 2005 format. In order for a smooth transition with this vendor Pharmacist, pharmacy software vendors, and/or Pharmacy Corporations will need to establish an account in order to process the data collection. To establish an account, please contact **Infinite Solutions immediately at their telephone number 916 641 0500 (main office) or 916 679 5720 (direct CURES support) or email them at curessupport@4infinitesolutions.com for technical support.** Their mailing address is 5, Parkcenter Drive, Suite 110, Sacramento California 95825.

You may also visit Infinite Solutions, Inc.'s website at **www.4infinitesolutions.com/cures** where you can find information about the submission of data to BNE through Infinite Solutions, Inc. beginning January 01, 2009. If you have any questions or need further information you may also visit the Attorney Generals website at www.ag.ca.gov or you may contact the CURES Program at (916) 319-9062. We anticipate a smooth transition. Thank you for your continued cooperation.

Sincerely,

Katherine Ellis

KATHERINE ELLIS, Manager
Bureau of Narcotic Enforcement

Attachment 9

Senate Bill 389 Mandatory Fingerprinting

SENATE BILL No. 389

Introduced by Senator Negrete McLeod

February 26, 2009

An act to amend Section 144 of, and to add Sections 144.5 and 144.6 to, the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 389, as introduced, Negrete McLeod. Professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a board to suspend or revoke a license on various grounds, including, but not limited to, conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued. Existing law requires applicants to certain boards to provide a full set of fingerprints for the purpose of conducting criminal history record checks.

This bill would make that fingerprinting requirement applicable to the Dental Board of California, the Dental Hygiene Committee of California, the Professional Fiduciary Bureau, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the State Board of Chiropractic Examiners. The bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would require licensees to certify compliance with that requirement, as specified, and would subject a licensee to disciplinary action for making a false certification. The bill

would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 144 of the Business and Professions Code is amended to read:

144. (a) Notwithstanding any other provision of law, an agency designated in subdivision (b) shall require an applicant *for a license* to furnish to the agency a full set of fingerprints for purposes of conducting criminal history record checks *and shall require the applicant to successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice as provided in subdivision (c) or as otherwise provided in this code.* ~~Any agency designated in subdivision (b) may obtain and receive, at its discretion, criminal history information from the Department of Justice and the United States Federal Bureau of Investigation.~~

(b) Subdivision (a) applies to the following:

(1) California Board of Accountancy.

(2) State Athletic Commission.

(3) Board of Behavioral Sciences.

(4) Court Reporters Board of California.

(5) State Board of Guide Dogs for the Blind.

(6) California State Board of Pharmacy.

(7) Board of Registered Nursing.

(8) Veterinary Medical Board.

(9) Registered Veterinary Technician Committee.

(10) Board of Vocational Nursing and Psychiatric Technicians.

(11) Respiratory Care Board of California.

(12) Hearing Aid Dispensers ~~Advisory Commission~~ *Bureau.*

(13) Physical Therapy Board of California.

(14) Physician Assistant Committee of the Medical Board of California.

(15) Speech-Language Pathology and Audiology Board.

(16) Medical Board of California.
(17) State Board of Optometry.
(18) Acupuncture Board.
(19) Cemetery and Funeral Bureau.
(20) Bureau of Security and Investigative Services.
(21) Division of Investigation.
(22) Board of Psychology.
(23) ~~The~~ California Board of Occupational Therapy.
(24) Structural Pest Control Board.
(25) Contractors' State License Board.
(26) Bureau of Naturopathic Medicine.
(27) Dental Board of California.
(28) Dental Hygiene Committee of California.
(27) Professional Fiduciaries Bureau.
(28) California Board of Podiatric Medicine.
(29) Osteopathic Medical Board of California.
(30) State Board of Chiropractic Examiners.

~~(c) The provisions of paragraph (24) of subdivision (b) shall become operative on July 1, 2004. The provisions of paragraph (25) of subdivision (b) shall become operative on the date on which sufficient funds are available for the Contractors' State License Board and the Department of Justice to conduct a criminal history record check pursuant to this section or on July 1, 2005, whichever occurs first.~~

(c) Except as otherwise provided in this code, each agency listed in subdivision (b) shall direct applicants for a license to submit to the Department of Justice fingerprint images and related information required by the Department of Justice for the purpose of obtaining information as to the existence and content of a state or federal criminal record. The Department of Justice shall forward the fingerprint images and related information received to the Federal Bureau of Investigation and request federal criminal history information. The Department of Justice shall compile and disseminate state and federal responses to the agency pursuant to subdivision (p) of Section 11105 of the Penal Code. The agency shall request from the Department of Justice subsequent arrest notification service, pursuant to Section 11105.2 of the Penal Code, for each person who submitted information pursuant to this subdivision. The Department of Justice shall charge a fee sufficient to cover the cost of processing the request described in this section.

SEC. 2. Section 144.5 is added to the Business and Professions Code, to read:

144.5. (a) Notwithstanding any other provision of law, an agency designated in subdivision (b) of Section 144 shall require a licencee who has not previously submitted fingerprints or for whom a record of the submission of fingerprints no longer exists to, as a condition of license renewal, successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice as provided in subdivision (d).

(b) (1) A licensee described in subdivision (a) shall, as a condition of license renewal, certify on the renewal application that he or she has successfully completed a state and federal level criminal offender record information search pursuant to subdivision (d).

(2) The licensee shall retain for at least three years, as evidence of the certification made pursuant to paragraph (1), either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those licensees who did not use an electronic fingerprinting system, a receipt evidencing that the licensee's fingerprints were taken.

(c) Failure to provide the certification required by subdivision (b) renders an application for renewal incomplete. An agency shall not renew the license until a complete application is submitted.

(d) Each agency listed in subdivision (b) of Section 144 shall direct licensees described in subdivision (a) to submit to the Department of Justice fingerprint images and related information required by the Department of Justice for the purpose of obtaining information as to the existence and content of a state or federal criminal record. The Department of Justice shall forward the fingerprint images and related information received to the Federal Bureau of Investigation and request federal criminal history information. The Department of Justice shall compile and disseminate state and federal responses to the agency pursuant to subdivision (p) of Section 11105 of the Penal Code. The agency shall request from the Department of Justice subsequent arrest notification service, pursuant to Section 11105.2 of the Penal Code, for each person who submitted information pursuant to this subdivision. The Department of Justice shall charge a fee sufficient to cover the cost of processing the request described in this section.

(e) An agency may waive the requirements of this section if the license is inactive or retired, or if the licensee is actively serving in the military. The agency may not activate an inactive license or return a retired license to full licensure status for a licensee described in subdivision (a) until the licensee has successfully completed a state and federal level criminal offender record information search pursuant to subdivision (d).

(f) With respect to licensees that are business entities, each agency listed in subdivision (b) of Section 144 shall, by regulation, determine which owners, officers, directors, shareholders, members, agents, employees, or other natural persons who are representatives of the business entity are required to submit fingerprint images to the Department of Justice and disclose the information on its renewal forms, as required by this section.

(g) A licensee who falsely certifies completion of a state and federal level criminal record information search under subdivision (b) may be subject to disciplinary action by his or her licensing agency.

(h) This section shall become operative on January 1, 2011.

SEC. 3. Section 144.6 is added to the Business and Professions Code, to read:

144.6. (a) An agency described in subdivision (b) of Section 144 shall require a licensee, as a condition of license renewal, to notify the board on the license renewal form if he or she has been convicted, as defined in Section 490, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

(b) The reporting requirement imposed under this section shall apply in addition to any other reporting requirement imposed under this code.

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Attachment 10

DCA Policy Statement
Interim Suspension Orders

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR
DIVISION OF LEGAL AFFAIRS
1625 N. Market Blvd., Suite S 309, Sacramento, CA 95834
P (916) 574-8220 F (916) 928-7984 |

MEMORANDUM

DATE: December 15, 2008

TO: Executive Officers
Executive Directors
Registrars
Bureau Chiefs

FROM: **DOREATHEA JOHNSON**
Deputy Director
Legal Affairs

SUBJECT: **Interim Suspension Orders**

It is the purpose of the Department of Consumer Affairs (DCA) to ensure that those businesses and professions under its jurisdiction (hereafter licensee) are adequately regulated in order to protect the public health, safety, and welfare of the people of California. It has been a longstanding policy of the department to encourage the practice of the licensing agencies, to use Interim Suspension Orders and PC 23s when the conduct of a licensee is such that the board cannot afford to wait for the completion of administrative process, following the filing of an accusation, before taking action to ensure the safety of the general public. This memo is to reaffirm the department's position with respect to the use of these proceedings.

When licensees engage in conduct that poses an imminent risk of serious harm to the public health, safety, and welfare, it is the policy of the DCA to act swiftly and efficiently to protect the public by applying the provisions of Business and Professions Code section 495, relating to interim suspension, and Penal Code section 23, relating to criminal probation against licensees. To this end, every board, bureau, and commission in the DCA (licensing agencies) shall: (1) institute proceedings for ordering the interim suspension of a license or imposing license restrictions when such action is warranted; and (2) make recommendations regarding specific conditions of criminal probation pursuant to Penal Code section 23 for persons licensed under the provisions of the Business and Professions Code.

A. Interim Suspension Order

DCA expects its licensing agencies to seek an ISO pursuant to Business and Professions Code section 494 whenever a licensing agency can meet the requirements of that section by demonstrating both of the following:

(1) There is a preponderance of evidence that a licensee has engaged in acts or omissions constituting violation of the Business and Professions Code or has been convicted of a crime substantially related to the licensed activity; **and**

(2) Based on a ***preponderance of evidence*** it has been determined that permitting the licensee to continue to engage in licensed activity, or permitting the licensee to continue in licensed activity or practice without restrictions, ***would endanger*** the public health, safety, or welfare.

Factors to Consider When Deciding Whether to Issue an ISO

In assessing whether it can meet the requirements set forth in section 494, a licensing agency will need to answer the following questions:

- Is the alleged conduct or conviction substantially related to the occupational license? Each licensing agency must be guided by its own statutes and regulations in determining whether there is a substantial relationship between an act or crime and the qualifications, functions or duties of a particular license.

- How much time has passed since the conduct at issue? The recency of the conduct goes to the question of whether the licensing agency can demonstrate by a ***preponderance of the evidence*** that permitting the licensee to continue to engage in licensed activity, or permitting the licensee to continue in licensed activity or practice without restrictions, ***would endanger*** the public health, safety, or welfare. This determination necessarily depends on the specific facts and circumstances of each case and the character and nature of each licensed occupation. Generally, to immediately order the suspension or restriction on a license, a licensing agency must be able to provide evidence of imminent potential harm to the public either based on other similar acts by a licensee or on the fact that the conduct occurred a very short time ago.

- Is the licensee incarcerated? Is the licensee going to be released soon from custody? If so, a Penal Code section 23 recommendation may be more appropriate and a more efficient use of the licensing agency's resources.

- If the licensee was convicted of a crime, how old is the conviction and have there been any more recent complaints of a similar nature against the licensee? If the conduct that led to the conviction is recent, then an ISO is more likely to be successful.

- What is the nature of the crime or act? How egregious is the conduct? For example, a licensing agency should seek an ISO where the conduct or act is very recent and involves one of the following:

  ---Licensed health care provider is accused of being under the influence of drugs or alcohol while treating patients.

  --Licensed health care provider is charged with DUI and the blood alcohol level is very high—e.g., .18 or greater.

  --Licensed health care provider allegedly has a consistent pattern of substance abuse.

  --Licensed health care provider has allegedly engaged recently in sexual misconduct with or sexually assaulted a patient.

  --Licensed security guard is recently convicted of a lewd act with a minor and will soon be released from custody.

  --Licensed health care practitioner is arrested for sexual assault against a patient.

  --Healing arts licensee is arrested for murder, aggravated rape or a similar type of assault.

  --Board has sufficient evidence to show that a licensed contractor's work on an ongoing project is substandard and is likely to compromise public safety.

This list is intended to provide some examples of situations where an ISO is appropriate. The list is not intended to be exhaustive, and you will need to review the specific facts and determine on a case-by-case basis whether an ISO should be requested. If you are unsure whether an ISO should be requested, please contact DCA Legal for assistance.

B. Penal Code section 23 Petitions and Hearings

Penal Code section 23 authorizes the DCA and its licensing agencies to appear in any criminal proceeding and make recommendations regarding specific conditions to be imposed on persons seeking to be released on their own recognizance, released on bail or being sentenced, including recommendations concerning conditions prohibiting the licensee from engaging in regulated licensed practice or restricting the licensee's

practice. In these circumstances, a licensing agency may recommend that a court order a licensee to surrender his or her license or practice under specified restrictions or conditions until such time as the criminal proceeding is concluded. At any stage during the criminal proceedings, a licensing agency may furnish pertinent information, make recommendations regarding specific conditions of probation, or provide any other assistance necessary to promote the interests of justice and protect the interests of the public.

A Penal Code section 23 petition may be presented in any court with appropriate jurisdiction during any criminal proceeding against a person licensed by DCA or one of its licensing agencies. A licensing agency that wishes to request the filing of a Penal Code section 23 petition must be able to demonstrate in the petition that the alleged crime is substantially related to the licensed activity and that suspending or restricting the license as a condition of bail, release or sentencing is necessary in order to ensure public safety while the criminal proceeding pending. The licensing agency's petition must delineate the specific recommendations by the licensing agency for suspending or restricting the license and explain how its specific recommendations would promote the interests of justice and protect the interests of the public while the criminal proceeding is pending. The following are some situations in which a licensing agency may wish to file a Penal Code section 23 petition:

---Licensed health care practitioner is arrested for being under the influence of drugs or alcohol while treating patients.

--Licensed health care practitioner is arrested for DUI and the blood alcohol level is very high -- e.g., .18 or greater.

--Licensed health care practitioner is arrested for sexually assaulting a patient.

--Licensed security guard is recently convicted of a lewd act with a minor and will soon be released from custody.

--Licensed health care practitioner is arrested for sexual assault against a patient.

--Licensed health care practitioner is arrested for murder, aggravated rape or a similar type of assault.

DCA encourages every licensing agency to file a Penal Code section 23 petition in the foregoing circumstances; e.g., whenever the likelihood of harm to the public would be great if the licensee was released and permitted either to practice or to practice without restrictions.

cc: Carrie Lopez
Scott Reid